CDS Connect Contract Year 3 Final Report





Final Report (Year 3)

CDS Connect

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CMS Alliance to Modernize Healthcare (The Health FFRDC) A Federally Funded Research and Development Center

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- MITRE CDS Connect Project Team
- AHRQ U.S. Preventive Services Task Force Leadership Team

Executive Summary

The mission of the Agency for Healthcare Research and Quality (AHRQ) is to produce evidence to make healthcare safer, higher quality, more accessible, equitable, and affordable and to work across the U.S. Department of Health and Human Services and in collaboration with other partners to make sure that the evidence is understood and used. A related AHRQ priority is to improve healthcare quality by accelerating the real-world clinical implementation of patient-centered outcomes research (PCOR) findings. AHRQ is also exploring the dissemination of PCOR findings as clinical decision support (CDS) resources that can be integrated with health information technology (IT), helping to move evidence into practice, while ensuring that CDS is more patient centered. ¹

Working with stakeholders across the healthcare community, AHRQ assists CDS developers and implementers to transform PCOR findings into CDS that provides patient-specific information and evidence-based knowledge to clinicians, patients, or other individuals. CDS includes processes and mechanisms that aim to deliver the right information, to the right people, using the right formats, in the right channels, and at the right times during workflow (often referred to as the "5 Rights" framework). Well-implemented CDS can inform healthcare decisions and improve the quality and efficiency of the care provided to patients.

An additional AHRQ goal is to make CDS more shareable and publicly available in a format compliant with health IT standards. To help realize that goal, AHRQ contracted with the Centers for Medicare & Medicaid Services (CMS) Alliance to Modernize Healthcare Federally Funded Research and Development Center (the Health FFRDC), operated by the MITRE Corporation, to build and maintain CDS Connect. The CDS Connect project aims to generate a systematic and replicable process for transforming PCOR findings into shareable, standards-based, publicly available CDS, and to develop prototype tools to facilitate this transformation process. CDS Connect systems, resources, and tools provide the framework for improving healthcare outcomes by: (1) making interoperable CDS expressions (or "artifacts") easier to create, (2) developing and sharing CDS artifacts and implementation guidance, (3) disseminating evidence-based research expressed as CDS, and (4) developing and releasing open-source health IT integration and implementation tools.

Clinicians today face an unending stream of new research findings, new or updated clinical practice guidelines, and best practices identified by peers that they must incorporate into daily practice. Transforming these large volumes of research into actionable knowledge that can be integrated into clinical care is a lengthy and expensive process that stretches the limits of what any one healthcare system can reliably accomplish on its own. Currently in its third year, the CDS Connect project provides an opportunity for healthcare organizations to share evidence-based knowledge expressed as CDS, enabling other organizations to leverage the publicly available expressions. The ability to share CDS expressions enhances efficiency by removing the need for subsequent organizations to develop CDS from "scratch." It also contributes to a

learning health community where CDS developers and implementers collaborate and enhance the shared resources.

CDS Connect is both a platform and a community of contributors and users, supported by open-source prototype tools for authoring, testing, implementing and sharing interoperable CDS. Central to CDS sharing is the CDS Connect Repository (the "Repository") of CDS knowledge artifacts. Through the Repository, CDS contributors and CDS consumers have equal access to CDS artifacts generated from cutting-edge CDS research, and clinical and regulatory guidelines. Additionally, organizations can leverage advanced technical resources and tools posted within artifacts to aid in the implementation of the CDS logic and secure information testing. Contributions to the Repository continue to increase, expanding the breadth of resources available to stakeholders across the Nation.

In year 1 of the project, the CDS Connect team developed and delivered the initial (alpha) and second (beta) versions of the Repository to AHRQ. Year 2 saw the release of the third (production) version, with continued refinement based upon feedback from the CDS Connect Work Group (WG) and CDS contributors. In year 3, a number of enhancements were made to the Repository, including the addition of an application programming interface (API) to streamline the import and export of CDS artifacts, enhancements to the metadata fields provided to describe each artifact, a new approach to browse and search for artifacts (i.e., artifact discovery), and expanded capabilities for user accounts. Section 6 of this document contains more detailed information on each of the enhancements, and Appendix B lists all of the contributed artifacts to date. The CDS Connect team also developed several prototype tools to facilitate the development, testing, and sharing of CDS artifacts. The open-source CDS Authoring Tool (AT), developed in year 1 and enhanced in years 2 and 3, allows non-software engineers to build standards-based CDS logic using the Health Level 7 (HL7) Clinical Quality Language (CQL) standard. The AT allows people unfamiliar with CQL to develop structured, well-formatted CDS artifacts through a user-friendly interface, leveraging interoperable standards so that CDS can be written to common specifications. In year 3, the CDS Connect team designed and released three phases of enhancements to the AT. Additional details about the AT and enhancements made can be found in Section 7 of this document.

The CDS Connect team also developed a new prototype tool, the <u>CQL Testing Framework</u>, and enhanced an existing prototype tool, <u>CQL Services</u>, in year 3. The CQL Testing Framework allows CQL authors to develop and run test cases for validating CQL-based CDS logic. CQL Services is an open-source service framework for exposing CQL-based logic using the <u>HL7 CDS Hooks</u> application programming interface. This capability allows implementers to integrate CQL-based CDS into systems that do not yet support CQL natively. All software developed through the CDS Connect project is open-source and freely available.

Each year, the CDS Connect team develops one or more CDS artifacts and pilots the artifacts in partnership with a healthcare organization to: demonstrate a repeatable process for translating evidence-based knowledge into interoperable CDS artifacts, identify potential challenges while

integrating the CDS artifacts into health IT systems and document lessons learned, test the CDS in a "live" environment and enhance the CDS expression as needed, and assess the Repository's capability to host and share the CDS artifact. An overview of the CDS artifacts developed each year can be found in **Table 1**.

In year 3, AHRQ selected patient-facing CDS in the domain of preventive health as the "use case" (i.e., scenario to frame CDS development). Working with a pilot partner, the CDS Connect team developed four patient-facing CDS artifacts based on U.S. Preventive Services Task Force (USPSTF) recommendations. This process included integration of the CDS artifacts into the pilot partner's health IT platform, providing real-world experience to inform the development and implementation of future CDS artifacts. Additional details on artifact development are found in Section 2, and more information on the pilot process is in Section 3.

Key to all streams of work, a <u>CDS Connect Work Group</u> (WG) was formed in year 1, and continued in years 2 and 3, to provide insight and advise the CDS Connect team on all aspects of CDS Connect work, including the identification and prioritization of key features and capabilities for CDS Connect systems and tools. Monthly WG meetings were attended by a broad array of CDS stakeholders (subject matter experts from across government, industry, academia, clinical settings, and nonprofits). In year 3, the WG members provided valuable input to the CDS Connect team on topics such as artifact development derived from the USPSTF recommendations, feedback on the CDS Connect Sustainability project to help shape the sustainability path and approaches, prioritization of prototype tool development and features, and feedback and ideas on enhancements to existing tools.

The CDS Connect leadership team also conducted extensive outreach via conference presentations, demonstrations, webinars, and strategic discussions to inform and maximize work efforts and increase adoption of the CDS Connect systems. Other <u>noteworthy milestones and accomplishments</u> as well as <u>stakeholder engagement activities</u> are described in more detail in additional sections of this document.

Throughout the third year of the CDS Connect project, the CDS Connect leadership team noted several valuable "lessons learned," impacting the year 3 work and providing valuable insight for future CDS efforts:

- 1. Lessons Learned affecting the development of and enhancements to CDS Connect prototype tools:
 - The CDS Connect team considered adding support for additional terminology servers in the AT; however, after further research and discussion with the CDS Connect WG, no candidate terminology servers were identified. Organizations using the AT should choose between using the Value Set Authority Center (VSAC) interface currently available or modifying the AT source code to use their own proprietary terminology server.

- VSAC was enhanced to add support for intensional value set creation, providing the
 ability to define value set codes using rules instead of enumerating every code.
 However, the VSAC Fast Healthcare Interoperability Resource (FHIR) API provided
 by the National Library of Medicine (NLM) has not been updated to support
 intensional value sets; therefore, the AT will not be able to display and execute them
 until this support is added.
- When using CQL libraries with dependencies, all references to the same CQL library must use the same version of that library; therefore, CQL authors must ensure matching versions in dependency libraries.
- The CQL Testing Framework prototype tool improved the efficiency and quality of CQL development for the CDS Connect technical team. The pilot partner, b.well, also benefitted through the receipt of bug-free CDS logic and automated test cases to streamline their testing efforts and ensure the accuracy of the CDS.

2. Lessons learned throughout the CDS pilot process:

- During the pilot, the CQL Services software failed to return results for several
 patients due to the very large volume of data. This was resolved by increasing the
 default size limit in CQL Services and adding the capability to edit the default size.
 Implementers should ensure that tests include validation for similar large volume test
 cases.
- Aggregating data from multiple sources presents great opportunities for coverage of required data, while introducing challenges in the completeness and specificity of the data, which may lack standard codes or specific data attributes. This compounds data mapping efforts, impacting resource needs as well as the implementation timeline. In general, the health IT industry would benefit from broader adoption of standardized terminologies and the FHIR data model, supporting increased interoperability and data aggregation and reducing mapping effort.
- Pilot technical team experience with evolving technology tools such as CQL,CDS
 Hooks, and FHIR should be considered when planning the implementation timeline
 and work effort in future pilot efforts.
- Future patient-facing CDS pilots should consider the importance of selecting a pilot partner with consumer/patient-facing experience and expertise, as well as ensuring that the pilot timeframe allows personalization and consumer/patient engagement opportunities to be realized.

3. Lessons learned affecting CDS artifact development:

The CDS Connect team desired to reuse value sets available on VSAC whenever
possible but found that there were inconsistencies in the definition and ongoing
maintenance, as well as duplicate value sets representing the same or similar

concepts. A governance process to help ensure the validity and maintenance of available value sets would increase trust and improve value set reuse, while decreasing the number of "similar" value sets created.

- The environmental scan performed early in the project provided key information to help shape the project strategy and decision making. The findings informed many aspects of the project, including the selection of the pilot partner and the focus of the preventive care CDS recommendations.
- Access to and collaboration with knowledge authors ensures the accurate translation and representation of the CDS logic and interventions.
- When defining clinical concepts in CDS logic, if the lookback period requires patient data recorded prior to the implementation of International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) on October 1, 2015, ICD-9-CM should be included in the concept definitions.
- 4. Feedback and engagement via the CDS WG and with other stakeholders provided major value to CDS Connect project efforts, informing the usefulness, usability, and longevity of CDS Connect resources and systems, while raising awareness and increasing contributions to the Repository and use of the AT.

These are discussed in greater detail in the <u>Lessons Learned</u> section of the document.

CDS Connect is helping to further AHRQ's vision of advancing evidence into practice through the dissemination of shared, interoperable CDS and the development of publicly available tools and resources to facilitate integration of CDS into health IT systems. CDS Connect is also contributing to a learning health community by documenting lessons learned across all project activities and publishing the lessons learned, along with recommendations for future efforts in the CDS domain. Collaboration with stakeholders will guide CDS Connect activities moving forward, enabling new efforts to effectively serve the healthcare community.

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Introduction

Clinicians today face an unending stream of new research findings, new or updated clinical practice guidelines, and best practices identified by peers that they must incorporate into daily practice. Transforming these large volumes of research into actionable knowledge that can be integrated into clinical care is a lengthy and expensive process that stretches the limits of what any one healthcare system can reliably accomplish on its own. The CDS Connect project, sponsored by the Agency for Healthcare Research and Quality (AHRQ), provides an opportunity for healthcare organizations to share evidence-based knowledge expressed as clinical decision support (CDS), enabling other organizations to leverage the publicly available expressions. The ability to share CDS expressions enhances efficiency by removing the need for subsequent organizations to start CDS development from "scratch." It also contributes to a learning health community where CDS developers and implementers collaborate and enhance the shared resources.

The CDS Connect project also develops prototype tools that make creating, testing, integrating, and implementing CDS in health information technology (IT) systems easier for healthcare organizations. Public access to these tools provides the healthcare community with resources to assist with translating evidence-based research into well-formatted, accurate, interoperable CDS expressions that can be presented to specific individuals (e.g., clinicians, patients) to inform decision making. The project team regularly engages with the CDS community to gain their insight on project activities. This insight informs decisions made by the project team to ensure that all systems, tools, and resources created by the CDS Connect project resonate with the community and serve their needs to deliver safe, high-quality healthcare.

Background

AHRQ is the lead Federal agency charged with improving the safety and quality of America's healthcare system. AHRQ is also charged with disseminating patient-centered outcomes research (PCOR) findings as CDS resources that can be integrated with health IT. This complementary charge accelerates the real-world implementation of evidence-based research, thus improving patient safety and the quality of care. AHRQ is approaching these missions by investing in research to develop the knowledge, tools, and data needed to enable individuals to make informed decisions by leveraging CDS. CDS is valuable because it provides patient-specific information and knowledge to clinicians, patients, and others at an impactful point in the decision-making process so the "targeted" individual can act on the information presented to them.

AHRQ contracted with the Centers for Medicare & Medicaid Services (CMS) Alliance to Modernize Healthcare Federally Funded Research and Development Center (FFRDC), operated by the MITRE Corporation, to launch an initiative promoting the dissemination and implementation of PCOR findings in 2016. Specifically, AHRQ tasked MITRE to generate a

systematic and replicable process for transforming PCOR findings into shareable, standards-based, publicly available CDS, and to develop prototype tools to facilitate this transformation process.

This project, named "CDS Connect," aims to: (1) improve the quality of CDS design; (2) accelerate the development of interoperable CDS logic expressions (or "artifacts"); (3) ensure public access to CDS artifacts; and (4) ease the integration of interoperably-expressed artifacts with health IT systems, such as electronic health records (EHRs). **Figure 1** displays the CDS Connect logo.

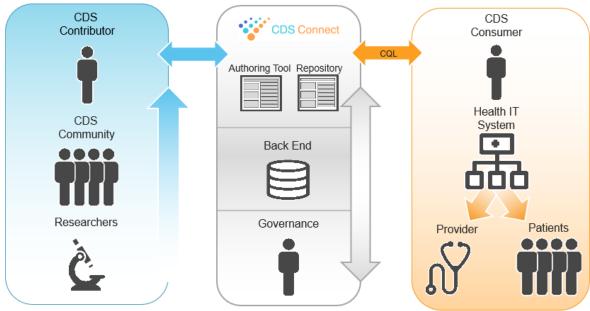
Figure 1. CDS Connect Project Logo



CDS Connect uses the term "artifact" to refer to a variety of CDS "types" or interventions. These interventions include alerts, which are commonly associated with CDS, but also include order sets, documentation templates, dashboards, infobuttons, and other functionalities. Considering CDS from a broad perspective of technical options is helpful because it enables developers to select a CDS approach (or "type") that is most intuitive and helpful to the individual receiving the CDS intervention.

Figure 2 provides a visual depiction of the CDS Connect "Concept of Operations." It portrays the CDS Connect Repository and CDS Authoring Tool (AT) as central, key facilitators to developing and sharing evidence-based CDS artifacts, along with a diverse group of individuals using the systems as contributors and consumers of the CDS (where the shared CDS is integrated in health IT systems and presented to clinicians and other targeted individuals).

Figure 2. CDS Connect "Concept of Operations"



The project has been underway for the past 3 years (i.e., September 2016-September 2019). Each year, project activities fall within seven different interrelated work streams (or "tasks").

CDS Connect Project Tasks

The CDS Connect project had seven tasks within which all work was performed. The following list enumerates and describes those tasks.

- 1. **Task Management:** engage with the CDS community and manage staff, budget, and deliverables.
- 2. **Develop PCOR CDS Artifacts:** create interoperable evidence-based CDS logic expressions for public sharing.
- 3. **Pilot PCOR CDS Artifacts:** partner with a healthcare organization to implement the new CDS in their health IT system for "live" use.
- 4. **Develop Prototype Tools for Sharing PCOR CDS Artifacts:** create new tools that aid CDS activities, such as testing or integration.
- 5. **Maintain Stakeholder Work Group:** lead monthly discussions with CDS stakeholders to gain their insight and suggestions regarding key project decision points.
- 6. **Host and Maintain Prototype Tools:** maintain and enhance the CDS Connect Repository with features informed by the CDS stakeholder community.
- 7. **Prototype Authoring Tool and Related Application Programming Interfaces (APIs):** maintain and enhance the CDS Authoring Tool with features informed by the CDS stakeholder community.

Additional details about the work performed within each task is provided in the Task Report section of this document. A list of key activities and work products for each task is provided in Appendix A.

CDS Connect Year 3 Milestones and Accomplishments

The CDS Connect project had noteworthy milestones and accomplishments during the third year of performance across the project tasks.

• Named as a finalist for the American Council for Technology-Industry Advisory Council (ACT-IAC) Igniting Innovation Award (a program that highlights innovative approaches to national problems across all government sectors) and presented with an **Innovation in Healthcare Award (Figure 3**).





• Recognized for the development and public release of CDS in the pain management domain at the White House <u>Blue Button Developers Conference</u> on July 30 (i.e., the "<u>Pain Management Summary</u>" <u>CDS artifact</u> and accompanying <u>Pain Management Summary Sustainable Medical Applications and Reusable Technologies [SMART] on Fast Healthcare Interoperability Resource [FHIR] app) (**Figure 4**).</u>





- Promoted patient engagement to empower patients to take action to improve their health and wellness by developing and piloting patient-facing preventive health CDS with b.well® Connected Health (b.well).
- Worked with stakeholders to publish 43 new evidence-based CDS artifacts on the <u>CDS</u> <u>Connect Repository</u>, to reach a current total of 56 artifacts. These resources are now publicly available to healthcare organizations across the Nation.
- Supported <u>CMS</u> and the <u>Da Vinci project</u> as part of the <u>initial piloting</u> of a
 Documentation Requirement Lookup Service (DRLS) CDS service. The CDS Connect
 Repository served as reference implementation for the pilot, which was demonstrated at
 the <u>Healthcare Information and Management System Society [HIMSS] 2019</u>
 <u>Interoperability Showcase</u> in the "Unlocking Patient Data" demonstration scenario.
- Published valuable open-source code for the <u>CQL Testing Framework</u> and <u>CQL Services</u> prototype tools. These tools enable CDS stakeholders to test and integrate CQL-expressed CDS more effectively.
- Provided AT training during a 90-minute national web conference attended by more than 300 people and now available for streaming on <u>AHRQ's Health IT YouTube channel</u>.

Task Reports

Task 1. Task Management

1.1. Operational Leadership

The leadership team that managed the CDS Connect project included a Project Leader (PL), Associate Project Leader (APL), Technical Lead, Clinical Lead, and respective Task Leads. The leadership team met throughout the period of performance to ensure work objectives were met and that emerging opportunities were discussed, prioritized, and integrated when appropriate. As warranted, the CDS Connect team worked with AHRQ to schedule and conduct both virtual and in-person site meetings at AHRQ. The team also identified and enlisted two subcontractors—Danny van Leeuwen (who provided a patient perspective to CDS Connect work) and b.well (the organization that piloted CDS Connect-developed artifacts)—to participate in project efforts and enrich outcomes based on their unique expertise and capabilities.

The CDS Connect PL managed project activities through biweekly agile "sprints." The PL planned work activities in 2-week increments. Project members described their assigned work activities at the beginning of each 2-week sprint period, then reviewed the work completed at the end of the sprint period, enabling the PL to monitor progress toward outlined objectives. The PL used <u>JIRA</u> to track sprint activities. JIRA is an open-source project management tool that provides support for agile software development processes and transparency. The agile approach to development and JIRA provided value for AHRQ and ensured high-quality work; it also allowed for better planning and management of competing priorities related to new capabilities for the CDS Connect software systems.

1.2. Stakeholder Engagement

The CDS Connect team invested significant time and attention into stakeholder outreach during year 3 of the CDS Connect project. Insight gleaned from the outreach influenced the development and refinement of CDS artifacts, and enhancements to the CDS Connect systems and tools. Formal stakeholder engagement occurred through the public WG as detailed in Section of this report. Informal stakeholder engagement occurred via in-person and virtual outreach and dissemination efforts (e.g., webinars, conference calls, conference participation, presentations).

CDS Connect leadership members attended a variety of conferences during year 3 of the CDS Connect project to raise awareness of the effort, encourage use of the publicly available systems and tools, and identify new opportunities for collaboration to further the project mission. Presentations at and participation in several key conferences and events generated or strengthened avenues for partnership.

- American Medical Informatics Association (AMIA) Conferences:
 - o <u>AMIA 2019 Annual Symposium</u>: AHRQ and CDS Connect leadership team members led three presentations at this conference.
 - AHRQ and the CDS Connect Technical Lead led a systems demonstration of the CDS Authoring Tool and Pain Management Summary SMART on FHIR app (a publicly available, open-source resource that facilitates integration and display of pain management CDS in health IT systems) titled, "Authoring and Integrating Interoperable CDS: CDS Connect Open Source Tools." This demonstration provided information to attendees on how the AT can be used to develop interoperable pain management CDS and how to use the SMART on FHIR app to implement the CDS logic in a health IT system.
 - The project PL participated in a panel presentation titled, "From Evidence to Action: Enabling Opioid Pain Management Guidelines Through Patient-Centered Clinical Decision Support" that discussed: (1) efforts to improve the clinical guideline creation process by developing a companion CDS expression of the guideline to facilitate implementation, (2) the value of shared CDS and the availability of open-source systems and tools created by the CDS Connect project, (3) lessons learned during the pilot implementation of the publicly available "Pain Management Summary" CDS artifact, and (4) attributes that promote trust in shared CDS and the systems that facilitate shared resources.
 - The project Technical Lead led a demonstration of the <u>Pain Management</u> <u>Summary SMART on FHIR app</u> at the AMIA/Health Level 7 (HL7) FHIR Applications Showcase, which enabled attendees to become familiar with the purpose, function, and open-source availability of the app.
 - o AMIA 2019 Clinical Informatics Conference (CIC):
 - AHRQ and a CDS Connect leader participated in a panel presentation titled, "To Share is Human! Advancing Evidence into Practice Through a National Repository of Interoperable Clinical Decision Support." The presentation described how a national repository of CDS can serve as a public resource for health care systems, academic researchers, and informaticists seeking to share and reuse CDS artifacts. The CIC program committee invited a subset of CIC presenters, including this panel, to submit their work for publication in AMIA's Applied Clinical Informatics journal. This article will heighten awareness of the opportunity and benefits that CDS Connect provides to host and share CDS resources.

• **HIMSS** Conferences:

o **HIMSS19**:

CDS Connect project members led demonstrations of the Pain Management Summary SMART on FHIR app while participating in the Interoperability Showcase as members of the Bundled Payments and Chronic Pain Management "use case" (or patient care scenario) (Figure 5). The Interoperability Showcase is a platform for demonstrating innovative interoperable health information exchange in support of a patient care scenario (in this case, a patient experiencing chronic knee pain despite having undergone a knee replacement and several months of rehabilitation and followup appointments). The demonstration provided tangible evidence of the usefulness and interoperability of CDS Connect resources, and how a summary view of relevant patient information can inform pain management decision making. CDS Connect leadership attendance also enabled project members to strengthen relationships with key stakeholders who attended the conference.

o 2019 Connected Health Conference:

CDS Connect project members led a presentation at the <u>Developer Lab</u> titled, "Developing and Sharing Standards-Based Clinical Decision Support" to introduce CDS Connect to attendees, discuss how to translate evidence-based knowledge in to structured code, and demonstrate CDS Connect systems and tools. Project member attendance at the conference resulted in the opportunity to engage with healthcare innovators pioneering new approaches to further health and wellness by delivering health information directly to patients (a target objective for the third year of the CDS Connect effort), and to schedule follow-on conversations to explore opportunities to collaborate in this area.



Figure 5. HIMSS19 Interoperability Showcase Participants

- 2019 Mobilizing Computable Biomedical Knowledge (MCBK) Annual Meeting
 - AHRQ and the CDS Connect Technical Lead led a presentation titled, "CDS Connect System Demonstration," which introduced attendees to the CDS Connect mission, systems, and tools.

• U.S. Preventive Services Task Force (USPSTF) Health IT Forum

o The CDS Connect PL and representatives from AllianceChicago (CDS Connect's year 1 pilot partner) and OCHIN (CDS Connect's year 2 pilot partner) presented insight on their experience using shared, publicly available CDS expressions to spur attendee discussion and generate considerations for USPSTF strategic planning efforts.

• AHRQ Health IT training seminar

AHRQ and CDS Connect leaders presented "<u>The Clinical Decision Support</u>
 <u>Authoring Tool: A National Web Conference</u>," to introduce new AT users to the
 tool and highlight the tool's capability to generate standards-based, interoperable
 CDS expressions.

The CDS Connect project team established and maintained collaboration with a wide range of stakeholder groups by engaging with individuals and organizations at conferences, scheduling and hosting discussions, responding to email outreach, and facilitating complimentary efforts, when able (e.g., the CMS and DaVinci DRLS effort). The stakeholders include:

- Federal agencies (e.g., Office of the National Coordinator for Health IT, CMS, Centers for Disease Control and Prevention [CDC], Veterans Health Administration [VHA], Substance Abuse and Mental Health Services Administration)
- Academic institutions (e.g., University of North Carolina, Vanderbilt, Stanford, University of Denver)
- Research organizations (e.g., Research Triangle Institute-University of North Carolina)
- Healthcare systems (e.g., Children's Hospital of Philadelphia, University of Pennsylvania Health System);
- Preventive health subject-matter experts (SMEs) (e.g., Dr. Alex Krist, Dr. Justin Mills, Dr. Howard Tracer)
- Primary care health innovators (e.g., One Medical, Crossover Health); health knowledge efforts (e.g., Healthcare Services Platform Consortium [HSPC], MCBK)
- Interoperability and terminology teams (e.g., Da Vinci, SOLOR)
- EHR vendor organizations (e.g., Nextgen)
- Technology companies (e.g., Google, Microsoft, Apple, Amazon)
- Health center-controlled networks (e.g., AllianceChicago and OCHIN)
- Patient advocate (Danny van Leeuwen)

In addition, CDS Connect members collaborated with the <u>Patient-Centered CDS Learning</u> <u>Network</u> (PCCDS-LN), another AHRQ-sponsored project, to fully understand and implement their <u>Recommendations for Building and Maintaining Trust in Clinical Decision Support</u> <u>Knowledge Artifacts</u>⁶ on promoting and enriching trust in shared CDS.

1.3 Patient Perspective

Facilitating patient-centered care is central to the CDS Connect project. In patient-centered care, the patient and their healthcare team partner to plan and manage the patient's treatment and care. Patient-centered care compels the team to understand the patient behind the symptoms and interact in a way that affirms the patient's vitality and attends to the stresses and life circumstances of the patient. The CDS Connect team enlisted Danny van Leeuwen (a patient and caregiver activist empowering people toward their best health) to lend a patient perspective on project activities. Mr. van Leeuwen contributed important insight that improved several work products. For example, Mr. van Leeuwen:

- Collaborated on the notification text that is presented to patients in the four new preventive health CDS artifacts. His expertise enabled the team to word the information in a way that is relatable and meaningful to patients and empowers them to act on the recommended care.
- Developed a new blog that is posted on the CDS Connect website titled, "<u>Health Equity:</u>
 <u>A Key Component.</u>" The blog outlines the importance of considering equity during CDS design, development, and implementation (i.e., awareness of social, behavioral, physical,

- and other circumstances that might impact a patient's ability to consider or follow through on a suggested plan of care).
- Participated in WG calls and discussions to highlight patient-related concerns and perspectives with regard to discussion topics (e.g., how Repository metadata fields might be enhanced to promote trust in the posted artifacts).
- Collaborated on enhancements to Repository metadata text to further how the preventive health artifacts can be used to provide patient-centered information to individuals.

Task 2. Develop PCOR CDS Artifacts

Each year, the CDS Connect team develops one or more CDS artifacts in a specific clinical domain, implements the CDS in a healthcare setting's health IT system, and contributes the body of work to the CDS Connect Repository. An overview of the project's CDS development efforts over the past 3 years is provided in **Table 1**.

Table 1. CDS Development Overview

Project Year	1	2	3
Clinical domain(s)	Cholesterol management and cardiovascular disease (CVD) prevention	Chronic pain management	Preventive health
Guideline developer	USPSTF	CDC	USPSTF
Number of artifacts developed	6	1	4
CDS intervention type	Populated smart form	Dashboard summary	Notifications
Pilot partner	AllianceChicago	OCHIN	b.well Connected Health
EHR	GE Centricity	Epic	Multiple
CDS technology	Custom CQL-based CDS engine	SMART on FHIR	CQL Services
Provider environment	Community health center	Community health center	Multiple
Intended CDS target audience	Clinician	Clinician	Patient

The CDS Connect artifact development process demonstrates how evidence-based knowledge can be transformed into interoperable, codified knowledge representations (i.e., CDS artifacts) using HL7 standards. The CDS artifacts are shared publicly via posting on the CDS Connect Repository, enabling other healthcare organizations to build upon and adapt the CDS for their own use. The ability to share CDS expressions removes the need for subsequent organizations to start CDS development from "scratch" and eliminates duplicative effort.

Sharing CDS requires identifying the appropriate information, or metadata, that helps subsequent users fully understand the CDS that has been developed and contributed to the Repository by other organizations. The metadata fields help CDS contributors describe the purpose, intended population, evidence-based references, human-readable logic, cautions, pilot findings, and any other key information about their CDS artifact. Likewise, work products created during artifact development provide additional detailed information to potential users, and are supported as attachments (e.g., coded logic, test patients, implementation guides, or examples of intervention content). Enabling robust communication of artifact information enhances a Repository viewer's understanding of the artifact, and ultimately enhances trust in the artifact.

Central to CDS Connect artifact development is the need to ensure the CDS is created using interoperable standards, to facilitate sharing and integration in varied health IT systems. The HL7 FHIR data model is used to define the clinical concepts used in the CDS. The HL7 FHIR standard has gained considerable traction as a method to exchange data and increase interoperability across health IT systems. HL7 CQL, adopted by CMS for expressing electronic clinical quality measures (eCQMs), is used to express the CDS logic, providing the opportunity to harmonize logic used in both, and potentially reduce software development efforts.

2.1. Providing Preventive Health Recommendations as Patient-Facing CDS

AHRQ selected patient-facing CDS focused on preventive care as the use case (i.e., scenario within which to develop CDS) for year 3 of the CDS Connect project. Most CDS is designed to be integrated into clinical workflow, with the clinician as the primary target and user. However, patients and their caregivers are increasingly seeking health information to help guide them in their healthcare decisions and are also potential target audiences for CDS. Patient-facing, evidence-based CDS may ultimately be one of the most effective methods of improving health outcomes by providing evidence-based information directly to patients, and by connecting them to resources and tools.⁷

2.1.1 CDS Development Planning

Year 3 began with an environmental scan of the preventive health domain, focusing on the USPSTF preventive health recommendations, existing publicly available patient-facing resources to support preventive health, and innovative approaches to delivering information to patients via technology. The team used that knowledge to shape CDS approaches for delivering patient-facing preventive health recommendations and to inform the selection of potential pilot organizations. Key findings included:

- USPSTF recommendations are used as an evidence-based source for other initiatives (e.g., eCQMs, Healthcare Effectiveness Data and Information Set measures).
- Coverage of related preventive services is mandated through the Patient Protection and Affordable Care Act, which required insurance plans to cover preventive services without any patient cost sharing, including all of the USPSTF "A" and "B" recommendations.⁸

- Many EHR vendors and healthcare organizations have already implemented CDS for preventive care (e.g., USPSTF "A" and "B" recommendations), potentially reducing the need for organizations using vendor systems to implement redundant or competing CDS.
- Employers are increasing their focus on employee health and wellness and are expanding traditional models of care as well as health insurance offerings. Patient-facing CDS may integrate well with this new focus.
 - Employers are moving away from a historical model of focusing solely on occupational health hazards and exposures. This transition is fueled by an increasingly competitive job market, the association of wellness and productivity, the requirement to provide health insurance to employees, and the increasing cost of health coverage.⁹
 - O As employer self-insurance grows in popularity, employers are offering more extensive healthcare services on site (e.g., through health clinics offering pharmacy, specialty, or ancillary clinical services). ¹⁰ Mobile technology plays a big role in this trend, providing the platform for employees to receive real-time lifestyle coaching and track their progress in managing their health.

Several approaches were drafted for delivering preventive health CDS via a patient portal, personal health record, or health wellness website or app. These approaches were discussed with healthcare organizations to explore their interest in collaborating on this work. Some of the proposed approaches included: (1) transforming one or more eCQMs into a CDS intervention, (2) expressing one or more of the newest USPSTF "A" or "B" recommendations as CDS interventions, and (3) creating CDS that addresses a business need (e.g., CMS requirement for providers to consult appropriate use criteria prior to ordering advanced diagnostic imaging services ¹¹).

After considering these approaches, a decision was made to focus on transforming one or more of the USPSTF "A" or "B" recommendations as CDS interventions, and to collaborate with the pilot partner to finalize the specific recommendations selected.

2.2 Preventive Health Recommendations Selected for CDS Development

As mentioned in Section 2.1, the USPSTF recommendations selected for CDS development were determined in collaboration with the pilot partner, b.well. b.well considered several factors when prioritizing USPSTF recommendations for implementation in their system: (1) preventive health CDS already available in their app, (2) the sensitivity of specific health topics (e.g., sexually transmitted diseases) and the potential need to survey their patients for information required by the CDS logic (e.g., detailed sexual and incarceration history), (3) the availability and accuracy of patient data required by the CDS logic, (4) the perceived impact on their end users, and (5) the perceived interest by the customer organizations that they serve. After thoughtful consideration

and evaluation, the project team agreed on the pilot implementation of CDS aligned with the following evidence-based recommendations:

- Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus 12
- Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults with Cardiovascular Risk Factors¹³
- Statin Use for the Primary Prevention of Cardiovascular Disease in Adults¹⁴

The CDS Connect clinical team investigated each recommendation to determine how they could best be represented as patient-facing CDS interventions. The result of this investigation shaped the CDS artifacts described in Section 2.3.

2.3 CDS Artifacts Developed in Year 3

The recommendations listed in Section 2.2 informed development of four new CDS artifacts. Each delivers recommendations and educational materials to individuals at risk for developing CVD and encourages them to discuss the information with their primary care provider to determine a plan of care. The new artifacts are briefly described in the following subsections.

2.3.1 Healthful Diet and Physical Activity for CVD Prevention

This artifact (referred to as *Diet and Activity* in this document) is derived from the USPSTF full recommendation statement for *Behavioral Counseling to Promote a Healthful Diet and Physical Activity for Cardiovascular Disease (CVD) Prevention in Adults With Cardiovascular Risk Factors*. The CDS logic identifies patients who are: (1) overweight or obese and (2) have at least one other risk factor for developing CVD (e.g., hypertension). The associated intervention raises awareness that the patient may have one or more risk factor(s) for heart disease and stroke and encourages them to talk to their primary care clinician about steps they can take to reduce their risk. For example, the patient might participate in behavioral counseling to promote a healthful diet and physical activity level.

2.3.2 Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Part 1, Screening

This artifact (referred to as *Abnormal Glucose: Screening* in this document) is derived from the USPSTF full recommendation statement on *Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus*. The artifact addresses the first part of the recommendation, specifically to screen patients for abnormal blood glucose levels as part of CVD risk assessment. The CDS logic identifies patients who are overweight or obese OR have other risk factors for developing abnormal glucose metabolism. Abnormal glucose metabolism is frequently associated with other cardiovascular risk factors. The associated intervention presents patients with information to raise awareness that they may have one or more risk factor(s) for developing high blood sugar or diabetes (which may lead to heart disease and stroke), along with how that may be impacting their health. It also encourages them to talk to their primary care clinician about being screened for abnormal glucose levels.

2.3.3 Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Part 2, Counseling

This artifact (referred to as *Abnormal Glucose: Counseling* in this document) is also derived from the USPSTF full recommendation statement on *Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus.* It represents the second part of the recommendation, related to offering intensive behavioral counseling to promote a healthful diet and physical activity level to individuals identified as having abnormal glucose levels and who may be at risk for developing CVD. The CDS logic identifies patients with abnormal glucose levels and other risk factors that may lead to diabetes (and potentially heart disease and stroke). The associated intervention presents targeted patients with: (1) educational resources for learning about the risks for developing diabetes and how to reduce those risks; (2) information on the role diabetes plays in CVD; and (3) encouragement to talk to their primary care physician about additional interventions, such as counseling to promote a healthy diet and physical activity level.

2.3.4 Statin Use for the Primary Prevention of CVD in Adults: Patient-Facing CDS Intervention

This artifact (referred to as *Statin Use: Patient-facing* in this document) is derived from the USPSTF full recommendation statement on *Statin Use for the Primary Prevention of Cardiovascular Disease in Adults: Preventive Medication*. The CDS logic identifies patients who have at least one risk factor for developing CVD (dyslipidemia, diabetes, hypertension, or smoking) and a calculated 10-year risk of a cardiovascular event of 10 percent or greater. The associated intervention presents targeted patients with: (1) information to raise awareness that they may have one or more risk factor(s) for heart disease and stroke; (2) educational resources about the risks for developing CVD and the role statin therapy has in reducing lipid levels and CVD risk; and (3) encouragement to talk to their primary care clinician about ways to reduce their risk, including starting a statin medication as a preventive measure.

There are two significant items to note regarding this artifact:

- 1. A key data requirement of the *Statin Use: Patient-facing* artifact is an individual's 10-year atherosclerotic cardiovascular disease (ASCVD) risk score, which is calculated by using the American College of Cardiology/American Heart Association pooled cohort equation (PCE). Since b.well did not have the PCE implemented in their system, they opted to pilot an additional CDS Connect artifact developed last year to enable the calculation of a 10-year ASCVD risk score (i.e., CMS's® Million Hearts Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10-Year ASCVD Risk). This change resulted in b.well piloting five artifacts, as opposed to four.
- 2. MITRE developed a clinician-facing artifact derived from the "Statin Use" recommendation during year 1 of the project (i.e., the Statin Use for the Primary Prevention on CVD: Clinician-Facing CDS Intervention artifact). The clinician-facing artifact uses the same inclusion and exclusion logic as the year 3 patient-facing artifact,

but it generates a distinct CDS intervention intended for a clinician with medication prescribing privileges. During year 3, the project team updated portions of the inclusion and exclusion logic used by both "Statin Use" artifacts. Along with publishing the new patient-facing artifact, the team published the updated clinician-facing artifact so potential implementers could benefit from the updated expression.

2.4 Knowledge Translation: From Recommendation Text to CDS Expressions

The translation of evidence-based knowledge into interoperable CDS artifacts requires careful analysis and specificity. Boxwala et al. developed a multilayered knowledge representation framework for structuring guideline recommendations as they are transformed into CDS artifacts. The framework defines four "levels" of representation, as depicted in **Figure 6** and described here:

Figure 6. CDS Artifact Maturity Process



- 1. **Narrative** text created by a guideline author (e.g., a recommendation statement presented as a sentence).
- 2. **Semistructured** text that describes the recommendation logic for implementation as CDS, often created by clinical SMEs. This serves as a common understanding of the clinical intent as the artifact is translated into a fully structured format by software engineers.
- 3. **Structured** code that is interpretable by a computer and includes data elements, value sets, and coded logic.
- 4. **Executable** code that is interpretable by a CDS system at a local level. This code will vary for each site.

The CDS Connect artifact development team employed a methodical approach to translating evidence from one "level" to the next, derived from a series of steps described in <u>Automating</u> <u>Guidelines for Clinical Decision Support: Knowledge Engineering and Implementation</u>, authored by Tso, et al. ¹⁶ The team also considered the CDS "5 Rights" framework (i.e., delivering the right information, to the right people, using the right formats, via the right channels, and at the right times during workflow) when designing and developing the CDS.²

<u>Sections 2.4.1</u> and <u>2.4.2</u> provide an overview of activities used to transform the narrative text into a semistructured CDS artifact and to an interoperable, structured CDS expression. <u>Section 2.4.3</u> describes how the structured logic was integrated into b.well's health IT environment.

2.4.1 Semistructured Representation of the USPSTF Recommendations

The USPSTF recommendations required additional precision for translation into semistructured CDS expressions. For example, the <u>Screening for Abnormal Blood Glucose and Type 2 Diabetes Mellitus</u> recommendation identifies women with a history of gestational diabetes who may be at increased risk for diabetes "at a younger age or at a lower body mass index." The team recognized the importance of incorporating this knowledge into the logic expression, but first had to determine how to interpret the phrase. This example demonstrates a challenging component of knowledge translation: interpretation of textual guidelines that may contain gaps in information or allow multiple interpretations.

The CDS Connect project team consulted with a USPSTF SME, who helped further define the guideline statements. Specifically, "at a younger age" was confirmed to mean ">=18 years old" (as opposed to ">=40 years old" for the overall guideline) and "at a lower body mass index" was confirmed to mean that the younger woman's body mass index (BMI) was not a factor to include in the logic (as opposed to a BMI >=25 kilograms/meters squared for other populations). The final semistructured logic phrase read, "OR patient is >=18 years old AND <=70 years old AND Gestational Diabetes."

Adding specificity to clinical recommendation statements to enable computation is an arduous and sometimes subjective process that requires SME input. The CDS development team spent a substantial amount of time researching the supporting evidence that informed each full recommendation statement and collaborated with USPSTF SMEs when needed to validate each logic statement to ensure that the semistructured representation aligned with the evidence base. The CDC "Adapting Clinical Practice Guidelines for the Digital Age" initiative is working to improve the computability of guidelines (among other objectives) by establishing a process for guideline authors to develop a digital version of their guideline as a companion to the narrative guideline text. This process, once mature, will reduce variations in implementation of the knowledge by minimizing subjective translations.

Each decision made during the knowledge translation process was outlined in a decision log contained within each artifact's *Implementation Guide* (posted with each artifact on the CDS Connect Repository). The documentation of decisions serves to provide transparency into decision points encountered during the development process and to promote trust in the integrity of the artifact. Artifact viewers can use the information to inform their implementation of the artifact and update the code to align with their organization's policy, preference, or distinct requirement, as needed. A full view of each semistructured logic statement is available within each artifact entry in the Repository and in each *Implementation Guide*.

The CDS development team designed each artifact's intervention in collaboration with a patient advocate advisor to be fairly general, enabling implementing organizations to expand upon and personalize the interventions based on their unique needs and patient population. Information provided to the patient translates the preventive care recommendation into lay language and provides additional resources in a user-friendly format and method. This user-friendly

information facilitates patient action by providing vetted resources and, in the case of the customized piloted CDS, an opportunity to provide personalized motivational messaging and logistical support for appointments and followup.

2.4.2 Structured Representation of the USPSTF Recommendations

Each semistructured representation was used to develop a structured representation of the knowledge (i.e., code that is interpretable by a computer, including data elements, value sets, and logic). The CDS development team authored each artifact using HL7 CQL, a data standard currently a Standard for Trial Use (STU). ¹⁷ CQL expresses logic in a human-readable format that is also structured enough for electronic processing of a query. It is used within both the CDS and eCOM domains.

The project team chose to use the FHIR Draft Standard for Trial Use 2 (DSTU2) data model in the CQL expressions, since two of the five pilot CDS artifacts were already expressed in this format, and b.well felt comfortable with this version of FHIR. As a result, the b.well pilot team was able to immediately begin integration of these artifacts within their system, saving valuable time and staff resources.

The project team further specified each clinical concept within the CQL logic using relevant standard terminology codes (e.g., medications were defined by RxNorm codes). Clinical SMEs evaluated existing value sets (groups of standard terminology codes) hosted in the Value Set Authority Center (VSAC) to determine if any aligned with the clinical intent of the recommendation. Existing value sets were reused whenever possible to minimize redundancy in VSAC. When an existing value set was not available, new value sets were developed to represent the required concept. During year 3, the CDS Connect team published 11 new values sets on VSAC and updated 6 previously authored value sets, totaling 17 new publicly available value sets shared in VSAC.

To help healthcare organizations considering adapting and re-using the CDS artifacts, the project team annotated CQL code with additional context and information where appropriate. This information helps identify where the project team faced choices and made assumptions, which other implementers will need to carefully assess. More information can be found in the detailed *Implementation Guide* that accompanies each artifact.

2.4.3 Executable Representation of the USPSTF Recommendations

Many commercial off-the-shelf health IT systems are unable to use CQL files natively and require a separate application or software to convert CQL code into an executable knowledge representation. Potential implementers of CDS Connect artifacts should work with the vendors of their respective health IT products to understand their readiness to implement CQL code. In many pilot settings, developers have worked around existing health IT limitations by implementing a web service wrapper around a CQL execution engine, such as CQL Services. ¹⁸

The CQL Services prototype tool was used in year 3 to facilitate integration of the five piloted artifacts. CQL Services allows integrators to interact with CQL artifacts using standardized communication patterns defined in the HL7 CDS Hooks specification. To use CQL Services in a secure fashion, b.well installed the CQL Services prototype tool software on their own platform infrastructure. Each night, b.well collected and formatted the required data elements for each user and sent them to the CQL Services installation for evaluation against the USPSTF recommendations. These CDS evaluation requests were sent individually per user and per CDS artifact. If the user met the inclusion criteria and did not meet the exclusion criteria, the response contained a CDS Hooks "card" containing a recommendation; otherwise the response was essentially empty, indicating that the recommendation was not applicable to that user. For more information on CQL Services, see Section 4.1 (CQL Services).

As mentioned previously, the interventions generated by the CDS Connect preventive health CQL logic are fairly general in nature, since most organizations will want to develop interventions that are specific to their organization's systems, branding, and resources. For example, b.well chose to integrate a hyperlink to a live chat service available within their organization that links the end user with real time resources. **Figure 7** provides an example of a CDS intervention implemented in b.well's app that enables the patient to act on the recommendation to speak with a primary care clinician.

Figure 7. Example of Encouragement to Set up an Appointment

Set up that appointment!

As you know, taking small steps to eat healthier, lose weight, and get more active is great for preventing diabetes. This is why the U.S. Preventive Services Task Force recommends that people at risk for diabetes work with their healthcare team on these areas.

It looks like you may be at higher risk for diabetes. So set up an appointment today to ask your doctor about how you can get started with counseling for healthy eating and physical activity.

We can help

If you don't have a doctor or need help scheduling your appointment, <u>use the live chat to contact our support team.</u>
We're always here for you!

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2.5 CDS Artifact Testing and Quality Reviews

The *Diet and Activity*, *Abnormal Glucose: Screening*, and *Abnormal Glucose: Counseling* artifacts were written using a test-driven development (TDD) approach. TDD is important for development, since it has been shown to produce software that is more robust and to contain fewer bugs. With TDD, a battery of test cases is created that defines the expected functionality of the software. An automated CQL testing framework developed under funding by AHRQ was used to enable the TDD approach for these artifacts. Referred to as the "CQL Testing Framework," this tool accepts test cases specified in YAML Ain't Markup Language (YAML) files, executes the artifact against each test case, and reports the success or failure of each test

case. Please refer to each artifact's *Implementation Guide* for more details on the TDD approach as well as specific information regarding test cases.

The Statin Use: Patient-Facing artifact followed a different testing approach, as the artifact was derived from an artifact developed in year 1 of the project (i.e., the Statin Use for the Primary Prevention on CVD: Clinician-Facing CDS Intervention artifact). This artifact was tested using an automated testing framework. This framework accepted test cases in a .csv (comma-separated value) file, executed the artifact against each test case, and reported the success or failure of each test case. Test cases were developed to investigate efficacy for basic expected functionality and to test the expected inclusion and exclusion criteria. Additional test information is available in the Statin Use: Patient-Facing CDS Implementation Guide.

Prior to release of the code to b.well, the CDS development team performed a quality review of each artifact to ensure that the semistructured and structured CDS representations aligned with the intent of the USPSTF guidelines. The team evaluated: value set selections, "clinicalStatus" and "verificationStatus" FHIR specifications, lookback periods, parameters, lab values, alternative expressions of clinical concepts, and each item that made the CDS expression deterministic and computable. CQL code annotations were added, when indicated, to ensure contextual decisions were communicated in key sections of CQL code. Items identified for revision were peer reviewed by the full multidisciplinary team. Once validated by all members of the artifact development team, the artifact was approved for release to b.well for the pilot implementation.

2.6 Artifact Enhancements and Pilot Implementation

The b.well and MITRE pilot teams identified two opportunities to enhance the structured CDS expression before public release of the code. Both involved updates to the way that clinical concepts were defined by standard terminology codes. Specifically, b.well identified valid International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes that represented "gestational diabetes" and "polycystic ovary syndrome" in their system and the valid codes were not included in the initial code definition. This illustrates a valuable finding included in the Lessons Learned section related to inclusion of ICD-9-CM codes based on the lookback period defined in CDS specifications. These valid codes were incorporated into a new version of the logic prior to publishing it on the Repository.

Further details on pilot artifact implementation are included in the *Pilot Report*, which outlines all aspects of the pilot (e.g., the implementation plan, technical integration process, enhancements to the logic informed by pilot activities, quantitative and qualitative findings, and lessons learned). The *Pilot Report* accompanies each CDS Connect preventive health artifact in the CDS Connect Repository.

2.7 Challenges Encountered During Artifact Development

Artifact development is complex, requiring significant expertise and research to create reliable and accurate CDS. It is best accomplished with a multidisciplinary team composed of clinical SMEs, end users, informaticists, and software engineers. Challenges often arise during the development process, forcing the development team to make informed decisions on how to best overcome the identified issues.

The CDS development team encountered the following challenges during creation of the patient-facing preventive health CDS artifacts:

- Ensuring proper translation of narrative guidelines to structured CDS expressions:

 Narrative guidelines can be intentionally vague if the reviewed research does not warrant a firmer statement, but vague text makes translation challenging and opens the door to varied interpretations of the same guideline. Divergence from the intent of the guideline jeopardizes the validity and evidence base of the CDS intervention. This risk was mitigated by engaging with USPSTF SMEs, who were able to validate the semistructured logic, thus ensuring what was piloted and publicly released aligned with their authored guidelines.
- Identifying appropriate value sets in VSAC and other internet locations to encode clinical concepts in CDS logic: Identifying appropriate value sets is challenging and resource intensive for numerous reasons: many value sets are missing metadata (requiring reverse engineering of the content to understand appropriateness for reuse), there is no tooling available to compare and reconcile value set content, and there is no mechanism to determine which value sets are deprecated and should no longer be used. The project team spent a tremendous amount of time analyzing over 100 different value sets to identify the most accurate and valid standard terminology definitions for the 44 different clinical concepts used in year 3 CDS artifacts. In the end, 11 new value sets were created for clinical concepts that were not previously represented in VSAC.
- Developing logic that accommodates variation in how data are captured and stored. Individuals developing CDS artifacts that are meant to be shared with many healthcare organizations using varied health IT systems cannot assume a uniform method of data capture. For this reason, shared CDS artifacts can be more complex than custom-developed CDS artifacts for specific implementation environments. For example, the concept of "behavioral counseling for a healthy diet and physical activity level" in CDS Connect artifacts is expressed as a: (1) referral, (2) procedure, and (3) encounter, to ensure that the logic would reliably identify evidence that counseling occurred in a patient record no matter how the data were captured and stored.

Task 3. Pilot PCOR CDS Artifacts

The CDS Connect project included a pilot to demonstrate the feasibility of implementing evidence-based CDS artifacts in a healthcare setting and to share lessons learned with future implementers. The scope of the pilot included engaging with a designated healthcare organization to implement four patient-facing preventive health CDS artifacts and an additional CDS artifact implemented to provide required data, for a multiweek intervention period. The CDS Connect *Pilot Report* provides additional details about the pilot program, including the implementation plan, technical integration process, CDS enhancement opportunities, quantitative and qualitative findings, and lessons learned.

In preparation for the pilot, the CDS Connect project team created a *Pilot Plan* outlining the scope, goals, and success factors of the pilot; key activities to accomplish to ensure pilot success; and a definition of the optimal pilot site characteristics and pilot site selection process.

The primary goals of the pilot were to: (1) translate evidence-based clinical guidelines into interoperable CDS artifacts; (2) inform and enhance the specification of the artifact(s) based on pilot integration, testing, and implementation findings; (3) gain an understanding of pilot stakeholder views as they experience pilot activities; and (4) contribute evidence-based CDS artifacts to the CDS Connect Repository.

3.1. Pilot Site Characteristics and Selection

The CDS Connect project team sought a pilot collaborator with technical readiness and a suitable healthcare environment to pilot the preventive health CDS. Key factors that influenced selection included identifying a pilot organization that was invested in: (1) supporting the patient/consumer decision-making process via CDS and (2) ensuring that the clinical domain (i.e., evidence-based preventive health recommendations formulated from one or more of the USPSTF recommendations) resonated with the organization. The ideal pilot site would provide patient/consumer-facing health IT capabilities and would identify preventive health as a high-value quality improvement imperative. Additional preferred characteristics included confirming that the required structured data were captured in the site's health IT system; ensuring the availability and support of clinical, operational, and technical staff, including the technical capability to implement the CDS; and verifying that the site had the organizational commitment and operational resources to meet pilot needs before, during, and after implementation.

After evaluating more than 20 different organizations, in collaboration with AHRQ, the project team determined that b.well[®] Connected Health met all defined pilot criteria. b.well offers a platform with personalized health management resources targeted to consumers to help them self-manage the entire healthcare process. b.well's mission is "to reduce the prevalence of chronic disease and make healthcare simple, personal, and affordable." Targeted customers are employers and health plans who sponsor the use of the b.well app for the people in their organizations, who are the actual end users of the b.well app. The consumer end users are incentivized to use the app through personalized educational information and "challenges."

b.well was awarded a subcontract through The MITRE Corporation for the performance period of March 13 through August 31, 2019.

Given the research and evaluation nature of the work and the project's goal to provide both specific and generalizable knowledge to a broad community of stakeholders, the project team engaged in the Institutional Review Board (IRB) process to ensure compliance with applicable human-subject protection policies. The MITRE IRB provided their approval, granting the project exempt status (i.e., the research does not exceed a minimal risk to human subjects and falls into an exempt category).²¹

3.2. Pilot Implementation Planning

The CDS Connect project team met with b.well several times in advance of the formal pilot kick-off meeting to begin discussion of the preventive health CDS and the CDS integration approach. b.well confirmed the data sources required by their platform, which included claims, EHRs, pharmacy benefits management (PBM), reference laboratories, and patient-generated health data (PGHD) (e.g., data from wearable devices, surveys and questionnaires, and mobile applications). The teams also discussed and finalized the USPSTF recommendations of highest priority to b.well, based on b.well's interest and need; the data available to meet the inclusion and exclusion requirements for each recommendation; and specific b.well concerns related to potentially sensitive topics for their end users (e.g., mental health or sexually transmitted diseases).

The project team drafted an initial pilot Work Plan establishing the proposed timeline and implementation details, as well as the critical path activities and risks. Once the pilot subcontract was finalized, a 2-day virtual kickoff meeting was conducted with key b.well and CDS Connect team members to review the pilot scope and work plan, review and refine the clinical aspects of the proposed USPSTF recommendations, and begin discussing the technical integration of the CDS within the b.well platform, as well as other related activities.

The project team also created a plan to evaluate the pilot. This plan included: (1) collection of qualitative data through an end-user survey at the end of the pilot (limited to nine end users due to the <u>Paperwork Reduction Act</u> [PRA] constraints) and (2) the creation of an Analytic Plan to provide quantitative data at pre-determined intervals during the pilot period (e.g., during the prepilot site implementation period, throughout the pilot, and after the pilot conclusion). Additional information, as well as the findings of both, are discussed in <u>Section 3.4.1</u>.

b.well and CDS Connect project teams participated in weekly technical and management calls from mid-April through August 2019. Throughout the pilot period of performance, both teams were readily available to address questions or issues as needed.

b.well decided to include all of their employer customers and associated end users in the pilot demonstration.

3.3. Pilot Site Technical Integration

Integration of the five CDS artifacts required the technical teams from both organizations to develop or customize software to integrate the CDS logic into b.well's IT platform. b.well and CDS Connect project teams considered different methods for integration and determined that using CDS Hooks was the best approach. CDS Hooks provided a plugin framework for custom CDS, and the CDS Connect team had already developed a CDS service framework, CQL Services, 18 that conformed to the CDS Hooks specification. b.well elected to run the CDS as a batch process during the night, to align with the current method they use for other "Care Needs" developed within their application. End users who qualified for the recommended preventive care based on their specific criteria (e.g., meets the inclusion criteria but not the exclusion criteria) were notified through either a push notification or an email.

Integration and implementation of the preventive health artifacts required significant effort from both teams. The CDS Connect project team was responsible for developing the CQL logic for the five artifacts, as well as any modifications to CQL Services; b.well was responsible for integrating and testing the artifacts within the b.well environment. The b.well technical team did not have prior experience using CQL and CDS Hooks and had only limited experience with FHIR. The CDS Connect technical team provided detailed documentation to assist with the integration efforts, monitored messaging and email communication to ensure real-time collaboration and discussion with b.well's technical team, and facilitated weekly technical meetings throughout the pilot time period.

The CDS integration also required a significant level of data analysis and mapping. Data on the b.well platform came from a variety of sources, including claims, EHR, PBM, reference laboratories, and PGHD (e.g., data from wearable devices, surveys and questionnaires, mobile applications, and other sources). The teams identified multiple gaps in the completeness and specificity of the required data available, and extensive data mapping was required by b.well to address many of these gaps. The CDS Connect project team provided detailed documentation to assist b.well with the integration and mapping efforts, including the creation of a *Data Requirements* spreadsheet that specified every data element, associated information, and mapping instructions if applicable.

The teams met throughout the course of development and implementation of the pilot integration to discuss requirements, architecture, technical approach, and outstanding issues. Additional detail on the technical integration can be found in the *Pilot Report*.

3.4 Analysis of the Preventive Health CDS Implementation

As mentioned previously, the preventive health artifacts were developed using a TDD approach, which helped to produce software that contains fewer bugs. ¹⁹ The technical team tested the artifacts throughout the development cycle using a comprehensive set of test cases and synthetic patient data. This testing provided assurance that the CQL logic was sound before beginning the pilot implementation and testing. After integration of the artifacts in the b.well environment was

completed, the technical team provided synthetic testing data for each artifact, and b.well performed end-to-end testing for each recommendation.

3.4.1 Qualitative and Quantitative Pilot Findings

The CDS Connect and b.well teams worked together to create a brief user survey for distribution to a limited number (based on PRA constraints) of b.well end users who had previously completed challenges related to the USPSTF CDS. Survey feedback helped the teams understand the perceptions and reactions of the surveyed end users to the preventive health CDS recommendations, although the limited number of respondents did not allow any statistically significant analytical data. Overall, the respondents seemed to think the preventive health information was relevant to them, with more than 65 percent of respondents either agreeing or feeling neutral. Although a high percentage (86 percent) of respondents reported that the information was not new to them, more than 70 percent reported that they planned to take action on the recommendations received, with only one respondent reporting that they did not plan to take action. In addition, more than 70 percent of respondents found the information easy to understand, and more than 55 percent thought the information would help improve their health, with 29 percent neutral.

Both teams also developed an Analytic Plan to provide quantitative data to help evaluate the effectiveness, accuracy, usefulness, and impact of the four patient-facing preventive health artifacts. The analytic reports were generated by b.well using their health data warehouse and tools. During the pilot, data were collected to ensure the CDS artifacts were functioning as expected. The results of the reports were compared with the results of the CDS logic for each recommendation. Reports created by b.well at the pilot conclusion provided quantitative data with the following high-level findings:

- During the 8-week clinical pilot, the total population of end users was 3,114, consisting of 54 percent male and 46 percent female individuals, with the majority of end users falling between the ages of 21 to 60.
- The number of unique users identified by the reports as meeting the inclusion criteria but not meeting the exclusion criteria is shown in **Figure 8.** Note that because of differences in the method and definition of counting certain conditions by b.well versus the more stringent definition in the CDS logic, there were some small differences in the final number of end users meeting the criteria.

Figure 8. Unique Users by Recommendation

RECOMMENDATION	USERS
Glucose Part 1, Screening	591
Glucose Part 2, Counseling	104
Healthful Diet and Physical Activity for CVD Prevention	456
Statin Use for the Primary Prevention CVD	7

- User Response rates to the intervention notifications were collected and analyzed:
 - Overall open rate (indicating that the end user opened the notification to view it): 24.52 percent (compared to 16.7 percent industry average according to b.well).
 - Overall click rate (indicating that the end user opened the notification and clicked on one of the links to go to the b.well app and view the associated challenge): 6.34 percent (compared to 2.1 percent industry average according to b.well).
- The following chart displays the measurable impact of the CDS in terms of completion of educational and action challenges on the b.well platform (**Figure 9**).

Figure 9. Challenges Completed by CDS Artifact and Challenge Content

Recommendation	Challenge	Total Users	Total User Completed	% Completed
Glucose Part 1, Screening	Get Screened for Diabetes	461	88	19%
Glucose Part 1, Screening	Schedule that Screening!	461	69	15%
Glucose Part 2, Counseling	Take Steps to Prevent Diabetes!	101	23	23%
Glucose Part 2, Counseling	You Can Lower Your Risk for Diabetes!	102	28	27%
Glucose Part 2, Counseling	Schedule that Appointment Today!	101	16	16%
Healthful Diet and Physical Activity for CVD Prevention	Give Your Heart Some Love	377	94	25%
Healthful Diet and Physical Activity for CVD Prevention	A Heart-Healthy Plate	377	91	24%
Healthful Diet and Physical Activity for CVD Prevention	Strong Body, Strong Heart	376	92	24%
Healthful Diet and Physical Activity for CVD Prevention	Take Action to Protect Your Heart	376	75	20%
Statin Use for the Primary Prevention CVD	Let's Talk about Statins and You	11	0	0%
Statin Use for the Primary Prevention CVD	Schedule That Appointment To Talk About Statins And You!	11	0	0%

The pilot achieved the goal of developing, refining, and verifying that the preventive health CDS performed as expected in a live healthcare setting, with: (1) successful integration with the b.well platform; (2) validation of the five preventive health CDS artifacts and associated logic; and (3) agreement by b.well that the CDS was valuable and contributed to their overall mission to reduce the prevalence of avoidable chronic disease, while putting consumers at the center of their healthcare.

The feedback and experiences of the b.well pilot team provided valuable input to the ongoing CDS Connect project from a CDS consumer and contributor perspective alike. AHRQ and the CDS Connect project team are tremendously appreciative of b.well's partnership and collaboration on this effort.

Task 4. Develop Prototype Tools for Sharing PCOR CDS Artifacts

As mentioned in the <u>Introduction</u> and <u>Background</u> sections of this report, the CDS Connect project team also developed prototype tools that make testing and integrating CDS in health IT systems easier for healthcare organizations. The tools serve as preliminary examples for demonstrating capabilities that can aid stakeholders in their efforts to utilize PCOR findings as CDS in clinical practice.

In year 3, the project team enhanced the CQL Services prototype tool and developed the CQL Testing Framework prototype tool.

4.1 CQL Services

In year 2, the CDS Connect team developed the <u>CQL Services</u> prototype tool. CQL Services is a web service framework for exposing CQL-based CDS logic over Representation State Transfer (or RESTful) APIs. A major focus of year 2 was providing support for <u>HL7 CDS Hooks</u> services. CDS Hooks is an API for invoking CDS from within a clinician's EHR workflow. It formally describes a pattern for interaction between an EHR and a CDS service, leveraging the HL7 FHIR standard and lessons learned from <u>SMART on FHIR</u>.

Although CQL Services was not the focus of the year 3 prototype tool development task, it was used in the year 3 pilot with b.well. During pilot activities, the project team identified several opportunities for enhancing CQL Services to address pilot requirements. These enhancements provided for easier installation and deployment of CQL Services, improved usability and debugging capabilities, and addressed several bugs identified in the software.

To provide easier installation and deployment, the team updated CQL Services to support building Docker images. These images allow CQL Services to be easily deployed as a "container" in a Docker ecosystem. ²² As a result, CQL Services can be deployed in a predictable manner on any operating system that supports the Docker daemon, as well as on popular cloud-based services. Since b.well used Docker to deploy CQL Services in their development and production environments, this update greatly benefited pilot integration activities.

The year 3 pilot required running multiple CQL artifacts concurrently within the same CQL Services instance. To better support this requirement, the CDS Connect team updated CQL Services to allow CQL libraries to be nested in multiple subfolders, so that each CDS artifact and its dependencies could be independently grouped together. In addition, the team enhanced CQL Services to support concurrent hosting of multiple versions of the same CQL library. The development team also addressed a bug that had previously prevented CQL Services from properly detecting value sets used in dependency libraries.

To implement certain advanced features for the integrated CDS, b.well needed to access other calculated values from the CQL results that were not represented by the standard fields in the returned CDS Hooks cards. To support this requirement, the CDS Connect development team updated CQL Services to allow integrators to leverage CDS Hooks extensions²³ to expose

calculated results from the CQL execution. The CQL Services configuration file now allows an arbitrary CQL statement to be mapped to specific extensions returned in the CDS Hooks cards. In addition, if the CQL contains statements for returning errors or warnings, those errors and warnings will also be included as extensions in the CDS Hooks cards.²⁴ CQL Services may also be configured to expose extensions on service definitions during CDS Hooks discovery.

During pilot testing, the b.well and CDS Connect teams realized that some patients' records contained so much data that they exceeded the maximum message size accepted by CQL Services (initially set to 100 kilobytes [KB]). When the maximum message size was exceeded, CQL Services returned an error instead of a valid CDS response. Recognizing that 100 KB was too small to support real-world scenarios, the CDS Connect team increased the default message size limit to 1 megabyte (MB). In addition, the team updated CQL Services to allow the message size limit to be more easily configured by CQL Services integrators.

The b.well team also reported that CQL Services returned an error message indicating a problem with the server whenever data was sent containing invalid measurement units. This is not the proper response for this situation; it is incorrect to imply an issue with the server when the issue is actually related to the data sent by the client. As a result, b.well had difficulty discerning when errors were due to client issues versus server issues. To address this problem, the CDS Connect team updated CQL Services to return the proper response to indicate that there is an issue with the data submitted by the client.

Throughout the process of updating CQL Services, the CDS Connect team pushed changes to AHRQ's private Bitbucket repository as well as the public-facing GitHub repository. At the end of year 3, AHRQ published CQL Services version 1.4.4 on GitHub; this version incorporated all of the changes detailed in this report.

4.2 CQL Testing Framework

AHRQ and the CDS Connect team explored several candidate options for a new prototype tool in year 3. One option was to build upon and expand the CQL Services prototype tool developed during year 2; this option would have gone beyond the updates described in the previous section, focusing on providing more robust support of the evolving CDS Hooks standard. A second option was to build a tool that could generate user-facing documentation from CQL files. This documentation would provide syntax highlighting and formatting of the CQL code, along with well-formatted annotations and other user-friendly features. Such generated documentation could be used standalone or embedded in CDS Connect and would help to increase the efficiency of CQL developers. A third option involved building a CQL testing tool that could be used as part of a TDD¹⁹ approach to writing more robust CQL code. AHRQ and the project team decided that the testing tool would provide the most value to the CDS community, and it became the focus of prototype tool development in year 3.

The CDS Connect development team built the CQL testing tool upon some of the same open-source software that underlies the CQL Services prototype tool. However, CQL Services is

focused on internal testing of CQL, rather than exposing it as a service. The new tool, named the <u>CQL Testing Framework</u>, allows a number of synthetic patient records to be defined alongside a set of expected results so that various aspects of a CQL-based CDS artifact can be tested. A very rudimentary form of the CQL Testing Framework had already existed in previous years of the CDS Connect project and had proven invaluable during CDS artifact development. The challenge in year 3 was to take the existing, but incomplete, CQL testing "engineering code," and turn it into software that could be useable and useful to those outside of the CDS Connect team.

As part of the initial effort, the team reviewed testing approaches that had been used to develop CDS Connect artifacts in previous years and extracted the supporting code into a standalone software application. The CDS Connect team then reorganized the existing code for better reusability and maintainability. As part of this effort, the team made the testing framework much more flexible by allowing users to customize its behavior via a simple configuration file. By the time the CDS Connect team delivered the initial (alpha) version of the prototype tool to AHRQ in January 2019, it could process test data and expected test results described in YAML Ain't Markup Language (YAML) format, and execute those test cases against CQL libraries. This version of the CQL Testing Framework supported only a limited set of FHIR DSTU2 data resources.

The project team used the alpha version of the CQL Testing Framework to facilitate a TDD approach during development of the CDS artifacts described in Section 2.3. As part of the TDD approach, the team defined a set of test cases for each artifact, with each test case consisting of a synthetic patient record along with the expected outputs from the CQL logic. The CQL was then developed and not deemed "complete" until all of the tests passed. The CDS Connect team believes that the absence of CQL bugs identified during the pilot can be partially attributed to the TDD approach enabled by the CQL Testing Framework.

Year 3 pilot planning informed the next set of enhancements to the CQL Testing Framework. Prior to the start of pilot integration activities, it was unclear whether the preventive health CDS artifacts would be expressed using a FHIR DSTU2 or FHIR STU3 data model. Ultimately, it depended on the pilot organization and the capabilities of their systems. Existing CQL testing code already supported parts of FHIR DSTU2; however, there was a chance that a pilot organization might require FHIR STU3 (a newer version). To reduce project risk and be prepared for either scenario, the team enhanced the CQL Testing Framework to define test cases in FHIR STU3. In addition, the CDS Connect team expanded the types of FHIR resources supported within the CQL Testing Framework to fully cover all FHIR resource types used in the preventive health artifacts. Examples of the newly supported data types include: (1) FHIR resources such as FamilyMemberHistory, ProcedureRequest, and ReferralRequest; and (2) FHIR extensions on the Patient resource type. Finally, the CDS Connect team added the capability to export the test cases as CDS Hooks request files. These files contain the test case data in a format that can be sent to the CQL Services prototype tool to invoke the CDS logic. Similarly, the team

also added support for exporting the test cases as Postman "collections." Postman is a popular tool for testing web-based APIs, and collections provide an easy way to import a number of Postman tests. The exported CDS Hooks request files and Postman collections made it much easier for the b.well pilot partners to perform integration testing within their infrastructure.

The second (beta) version of the CQL Testing Framework included all of the above refinements and enhancements. AHRQ deemed the beta version of the CQL Testing Framework useful to the CDS community and instructed the CDS Connect team to prepare the code for open-source release. The CDS team prepared the CQL Testing Framework for open-source release by: (1) performing a security review; (2) enhancing the documentation to include new features and capabilities; and (3) adding the license, contribution policy, and code of conduct to the documentation. AHRQ released the CQL Testing Framework as open-source software on GitHub²⁶ on July 12, 2019. The project team also made it available as a library via the Node Package Manager (NPM) repository so that it can be accessed via the traditional NPM²⁷ or Yarn²⁸ dependency management mechanisms.

The third (production) release of the CQL Testing Framework included the ability to store test case components or resources in separate files, thereby allowing reuse across multiple test cases. With previous versions of the CQL Testing Framework, users were forced to frequently copy and paste if they had a large number of related test cases. The production release of the CQL Testing Framework removes this burden by allowing users to put common resources in separate files, which can then be referenced from within any test case.

In addition to implementing reusable resources, the production release of the CQL Testing Framework provides users with two methods for importing groups of resources into a test case. The first method allows a list of resources defined in a separate file to be imported into a single test case. For example, a test author might define a list of medication order resources that represent a common medication regimen. The author could then import that list of medication orders into any test cases where that medication regimen should be present in the record. This method is useful when test cases are complex and contain many resources that may be repeated across test cases. The second method also uses a list of resources defined in a separate file, but in this case, it creates a series of test cases from those resources. It does this by creating multiple copies of the main test case and then inserting a different resource from the external resource list into each copy. For example, a test author may wish to test CQL for which any of a number of risk factors qualifies a patient for the inclusion criteria. The author can create a list defining every possible type of risk factor and then use that list to generate a separate test case for each one. This approach ensures that the tests fully cover each corresponding branch of logic in the CQL. The second method is generally useful when the test author wants a group of similar test cases, each of which differs from the other by only a single resource.

The CDS Connect team delivered the production version of the CQL Testing Framework to AHRQ in August 2019; it can be found online in the <u>AHRQ CDS GitHub repository</u>.

Task 5. Maintain Stakeholder Working Group

The CDS Connect WG's primary mission is to provide insight and advise the CDS Connect team on all aspects of CDS Connect work, including the identification and prioritization of key features and capabilities for CDS Connect systems and tools. The WG was established to include a diverse representation of CDS stakeholders to ensure a range of perspectives are heard concerning this work. Members were identified through AHRQ and CDS Connect project team contacts and included representatives from key stakeholder groups such as SMEs in the domain of CDS development and tools; leaders in quality improvement, health IT, and academia; healthcare leaders with a background in CDS implementation and management; and other individuals identified by the project team, AHRQ, or WG members.

The CDS Connect team convened the WG in October 2017 and established an initial charter that detailed goals, objectives, governance structure, and operational procedures. During the first year of performance, the WG selected a Chairperson to work alongside a CDS Connect leader-facilitator. The same individual agreed to serve as Chairperson for year 2 and year 3. The Chairperson was responsible for co-creating a monthly agenda with the CDS Connect team and facilitating WG meetings.

The CDS Connect team reviewed and updated the existing WG charter at the beginning of year 3 to incorporate current WG goals, objectives, governance structure, and operational procedures. The primary objectives of the WG encompassed stakeholder feedback on various key aspects of CDS Connect project work. WG members:

- Reviewed demonstrations and documents, and provided recommendations concerning the structure, capabilities, features, and operation of the CDS Connect Repository, AT, and prototype tools; and reviewed and commented on the usability and suitability of these features and any proposed enhancements.
- Provided clinical, technical, and other related expertise to assist in the definition and evolution of CDS artifacts developed in year 3, including expertise and feedback in the domain of preventive health and USPSTF recommendations.
- Offered review and feedback on specific aspects of the CDS Connect pilot.

WG meetings were held to drive decisions to consensus, but assertions of opposing views were encouraged to ensure that all parties were properly heard and to strengthen the consensus view through subsequent discussion. The WG conducted virtual 1.5-hour monthly meetings with additional feedback provided through followup emails and calls when necessary. Meeting topics included the following:

- Proposed enhancements to the CDS Connect AT, Repository, and prototype tool development, including opportunities for WG members to provide their feedback and ideas.
- The future of CDS Connect and its sustainability.

- Related efforts, including the PCCDS-LN's Trust Framework Work Group (TFWG) recommendations, the CDC "Adapting Clinical Guidelines for the Digital Age" project, and the AHRQ Evidence-Based Care Transformation Support Initiative.
- Updates on CDS Connect artifact development and pilot activities.

WG meeting summaries and presentations are located on the WG page of the CDS Connect Repository.

Task 6. Hosting and Maintaining Prototype Tools

The CDS Connect Repository was the first prototype tool released by the CDS Connect team. The Repository hosts interoperable structured CDS expressions known as artifacts. The CDS artifacts hosted on the Repository include contributions developed by the CDS Connect team, as well as those from trusted third parties. The goal of the Repository is to demonstrate how evidence-based research can be more rapidly incorporated into clinical practice via shared CDS artifacts.

In year 1 of the project, the CDS Connect team developed and delivered initial (alpha) and second (beta) versions of the Repository to AHRQ. Year 2 saw the release of the third (production) version, which is <u>live on the internet</u> and publicly visible. The CDS Connect team further refined the Repository in year 2 based upon feedback from the CDS Connect WG.

6.1 Year 3 Repository Enhancements

Year 3 saw a number of additional improvements to the Repository, many of which were motivated by the needs of external third-party contributors and collaborators.

6.1.1 Application Programming Interface

Toward the end of year 2, the CDS Connect project team began collaborating with the Durable Medical Equipment (DME) Electronic Prescribing (eRx) project sponsored by the <u>CMS Center for Program Integrity</u> (CPI). A key component of this collaboration was an API for the CDS Connect Repository. Although the API existed in years 1 and 2 of the project, the collaboration with CPI required the team to expand and release the API as open-source software. The CDS Connect team focused on achieving these goals during the first quarter of year 3.

The CDS Connect API allows CDS artifacts to be uploaded and downloaded programmatically (i.e., using custom-developed software). Through this API, registered users can authenticate and communicate with the CDS Connect Repository using HyperText Transfer Protocol (HTTP) requests (the same technology used by web browsers to communicate with websites). The API enables these requests to be made using a simple JavaScript Object Notation (JSON) format representing the data to be exchanged. While the API itself is not an open standard, it adheres to the OpenAPI standard, ²⁹ so it can be more easily understood and integrated with other systems. The CDS Connect API is now available as an open-source project under an AHRQ CDS GitHub account.

In preparation for open-source release of the API, the development team reviewed and revised the underlying code, added documentation, and wrote a battery of automated tests. These tasks ensured that the software powering the API was of sufficient quality and maintained best practices in software development. The CDS Connect team delivered a security analysis and the source code to AHRQ in late November 2018. The code was approved by AHRQ in early December 2018, and posted on AHRQ's CDS GitHub page. ³⁰ A link was added to CDS Connect's Technical Resources page, ³¹ with the intention of making it easier for users to find the AHRQ GitHub page.

The CDS Connect team continued to collaborate with the DME eRx project team after the API was released as open-source software. In 2019 the DME team used the CDS Connect Repository in a small-scale pilot. Throughout the pilot, the API was the primary mechanism through which the Repository was accessed by the DME eRx team. To facilitate the effort, the CDS Connect team added three additional metadata fields to the CDS artifact content type in the Repository. These fields are meant to represent information pertaining to coverage requirements discovery, which is a key component of the DME eRx project pilot. In addition to fostering collaboration with CPI, adding these three metadata fields to CDS Connect provided a larger benefit by broadening the scope of the types of CDS, which are able to be represented in the Repository. These new fields were published to the open-source API codebase in January 2019.

Throughout year 3, several other updates to the CDS Connect API were published to the open-source codebase on GitHub. The first update involved adding descriptions to each of the metadata fields for the artifact content type. These descriptions were added in response to feedback from the TFWG report to facilitate trust in the artifacts shared by the Repository. The second update involved a change in how the open-source API code can be installed. For the initial release of the CDS Connect API, the software was installable as a custom module in Drupal, the open-source content management system that powers the Repository. Now the API can be installed in any Drupal project using a standard dependency management tool called Composer. In addition to expanding options for others to leverage the CDS Connect API code, it allows the CDS Connect team to decouple development of the API from the rest of the software that makes up the Repository.

The API also served as the focal point for collaboration with the VHA Knowledge-Based Systems (KBS) program office. The VHA KBS program office developed a large number of CDS artifacts, and the collaboration involved publishing many of them on the Repository. The CDS Connect team worked with VHA technical points of contact to ensure that all of the pertinent metadata was correctly associated to relevant fields in the Repository. The VHA team used the CDS Connect Repository API as the main mechanism for bulk upload of their artifacts, saving a considerable amount of time compared to the process of manually uploading the artifacts.

6.1.2 Artifact Discovery

The CDS Connect team devoted significant time in year 3 to the design and implementation of "Artifact Discovery," a new approach to browsing and searching artifacts on CDS Connect. First, the team provided a non-functional mockup of the design for review by the AHRQ government team. After revising the design based upon feedback from AHRQ, the CDS Connect team implemented a functional prototype of the Artifact Discovery design.

Drupal, the content management system that powers the CDS Connect Repository, provides the flexibility to implement the Artifact Discovery design in multiple ways, thus requiring investigation to determine the best approach. After careful review of the options, the team decided to implement the design as a module.³³ This approach greatly facilitated efficient collaboration on the implementation and simplified testing and deployment of the design. A screenshot of the new Artifact Discovery feature is shown in **Figure 10**.

AHRQ Home About AHRQ Contact AHRQ FAQ MEmail Updates Agency for Healthcare Research and Quality PATIENT-CENTERED OUTCOMES RESEARCH Clinical Decision Support Q Accelerating Evidence into Practice through CDS CDS Home Overview CDS Connect Learning Network Evaluation Funding Opportunities Artifacts Authoring Tool Community Welcome Artifact Discovery Q Search Artifacts **Explore CDS Connect Artifacts** NEW ARTIFACTS The most recently published artifacts. **Refugee Health Decision Support** Publisher: Centers for Disease Control and Prevention Refugees Public Health Neurosurgery: Radiculopathy (Lumbar Thoracic) Order Set Publisher: Veterans Health Administration Radiculopathy Primary Health Care Neurosurgery Statin Use for the Primary Prevention of CVD in Adults ■ EVENT-CONDITION-ACTION (ECA) RULE Publisher: The MITRE Corporation Preventive Health Services Primary Prevention Cardiovascular System ALL ARTIFACTS To search for artifacts across numerous criteria, use the search icon above. Otherwise, add topic(s) to filter this list of artifacts. Interventions for Unhealthy Alcohol Use: SmartSet for Note Oct 31 **Documentation, Referrals, and Medications** SMART DOCUMENTATION FORM

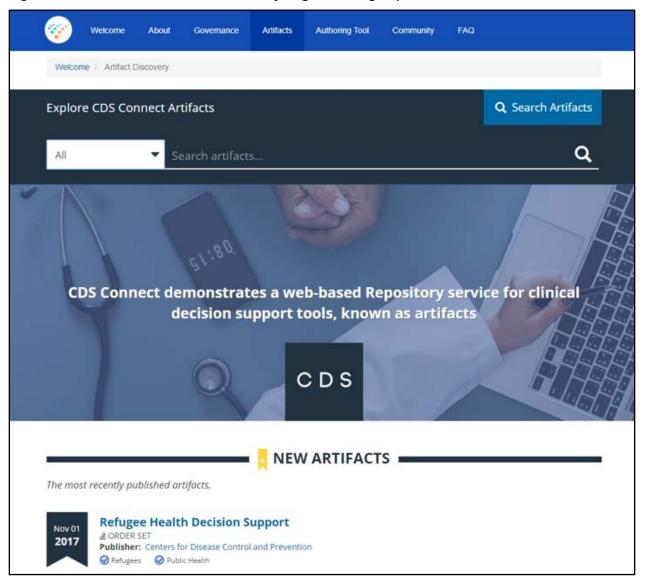
Publisher: RTI-UNC Evidence-based Practice Center 2018 Alcohol Drinking Primary Health Care Internal Medicine Screening and Interventions for Unhealthy Alcohol Use: Logic for Best Oct 31 **Practice Alerts** 2018 ALERT Publisher: RTI-UNC Evidence-based Practice Center

Figure 10. Screenshot of Artifact Discovery Page (https://cds.ahrq.gov/cdsconnect/artifact)

The two main components of the Artifact Discovery design are browsing and search. The CDS Connect Repository already had a basic, site-level search capability. The new Artifact Discovery search builds upon the Drupal 8 Search API module, which provides the potential for search functionality more comparable to what is found in the popular "brand name" search engines. While there are still opportunities for further enhancements, using the Search API module will allow for more scalability as the CDS Connect Repository grows. At the close of the first quarter

of year 3, the new search capability had been implemented in a prototype Artifact Discovery page. The CDS Connect team demonstrated this new search capability to the CDS Connect WG as a partially functional prototype, then refined the capability based upon WG feedback. The final live search box is shown in expanded form in **Figure 11**.

Figure 11. Screenshot of Artifact Discovery Page Showing Expanded Search Bar

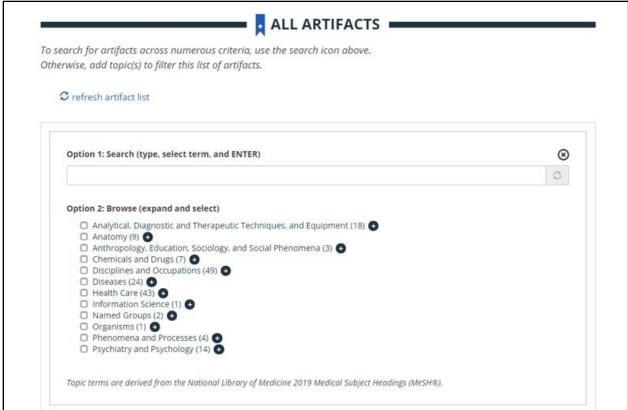


Although users could browse the CDS Connect Repository prior to the new Artifact Discovery approach, this entailed paging through a long listing of all artifacts in the Repository. The new approach in Artifact Discovery allows users to select and de-select topics of interest, which filters the list of artifacts displayed. Artifact Discovery also provides a highly visible section for showcasing the artifacts most recently added or updated in the Repository. This new approach provides users with a more intuitive way to examine the contents of the CDS Connect Repository. The approach also scales better as the number of artifacts hosted by the Repository

increases. As with the new search functionality, the project team demonstrated the new browsing capability to the CDS Connect WG near the end of the first quarter of year 3.

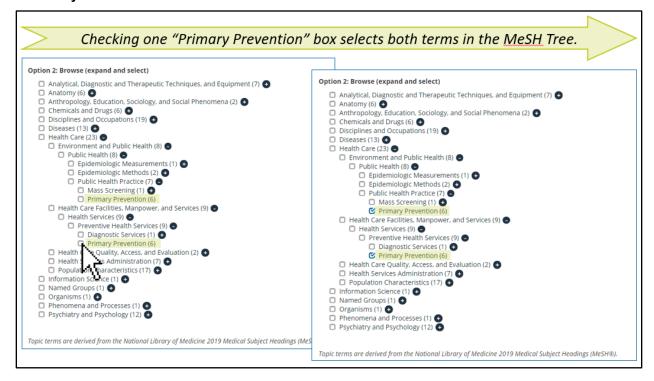
The new browsing approach uses topic tags based upon the Medical Subject Headings (MeSH) taxonomy published by NLM. MeSH provides a widely used and well-known vocabulary that can be used to tag artifacts on CDS Connect. The development team identified the vocabulary and integrated its large number of terms into the Repository. The new browsing capability resolves a longstanding issue with MeSH-based browsing by only presenting MeSH terms that are relevant to existing artifacts. This change is an important capability, since MeSH contains a large number of terms and presenting every term to the user would result in a poor user experience. Figure 12 shows a screenshot of the expanded topic filter, which provides two options for adding topics of interest. When a topic is added by a user, only those artifacts that have been tagged with that term appear.

Figure 12. Screenshot of Expanded Topic Filter (Browsing in Artifact Discovery)



As seen in **Figure 12**, users can add topics one of two ways: they can search via an autocomplete form (Option 1), or they can explore an expandable version of the MeSH taxonomy tree (Option 2). **Figure 13** shows an example of a partially expanded MeSH tree, along with a particular term being added to the topic filter. The figure also shows how individual MeSH terms display in multiple branches of the taxonomy tree.

Figure 13. Screenshots Showing Expanded MeSH Tree and Term Selection Process in Artifact Discovery



6.1.3 Expanded User Accounts

To help address some of the recommendations from the TFWG report, the CDS Connect team began an effort to expand user accounts on the CDS Connect Repository. These changes are the first phase of a set of capabilities meant to build greater trust in the Repository itself, as well as the shared CDS published on the Repository. The team designed, tested, and implemented the following capabilities during year 3:

- A new form allowing external parties to request a CDS Connect Repository account.
- The ability for registered users to subscribe for updates to specific CDS artifacts, organizations, and MeSH topics.
- The capacity for registered users to manage their subscriptions.
- The ability for CDS Connect administrators to target emails to particular users based upon their subscriptions or roles.
- Optional automated email notifications for when artifacts are marked as "Published" or "Needs Review."

These expanded user account capabilities were under review with AHRQ when this report was authored. They will be enabled for the general public when final approval is granted by AHRQ.

6.1.4 Maintenance and Miscellaneous Improvements

During the first quarter of year 3, the CDS Connect team developed a new Patient Perspective page³⁴ on CDS Connect, where blogs written by the CDS Connect patient advocate can be posted. The CDS Connect team reviewed the design for the new page with AHRQ, and then implemented and deployed the page with the first blog entry. A second blog entry was subsequently published in April 2019.

A number of other minor improvements were also deployed during year 3. Each external contributor has an organization page that lists pertinent information. Previously, each organization page only listed the five most recent artifacts contributed by that organization. The CDS Connect team updated the organization page structure so that all contributed artifacts were listed using a paging mechanism. This change helps to more clearly document the contributions for organizations that have authored many artifacts on CDS Connect.

The CDS Connect team also deployed a minor update to the administrative content page used by administrative editors to monitor the status of draft artifact contributions to the Repository. In the past, this page did not list revisions to previously published artifacts, which would sometimes make it difficult for administrative editors to determine when revised content needed to be reviewed. The deployed update changed the administrative content page so that it always shows the most recent revision of each CDS artifact on the Repository.

The CDS Connect team also completed a number of important software upgrades during year 3. Until May 2019, the Repository had been running Drupal version 8.5, which was reaching its end-of-life capacity. The team upgraded the Repository to Drupal version 8.7, the newest version available at the time this report was authored. The CDS Connect team also applied a variety security updates as needed throughout the year, always within a very short window following the release of urgent security patches. These actions were carried out so that the security posture of the Repository could be maintained.

During the first quarter of year 3, the CDS Connect team completed an in-depth analysis of the PCCDS-LN's *Recommendations for Building and Maintaining Trust in Clinical Decision*Support Knowledge Artifacts report, evaluating each of the 33 recommendations in 9 trust categories. The team developed a chart comparing the two evaluation frameworks used in the report, with the trust categories and identified recommendations for determining any gaps in the current state of CDS Connect. The team determined that many of the recommendations were already addressed via metadata fields enabled in the Repository and discussed potential solutions with AHRQ during a brainstorming meeting in December 2018. After developing a plan to address the approved solutions, the team began implementation of that plan in January 2019. The two main components of the plan included expanding user accounts and updating metadata descriptions for CDS artifacts, and expanding user accounts in both the new API and the legacy artifact authoring form. Although the descriptions of each field had been provided to external contributors in the past, having publicly available field descriptions as part of the API and

authoring form further addresses several of the key recommendations from the TFWG report.⁶ Examples of pertinent key recommendations from the TFWG report include:

- "Metadata state any known limitations, restrictions, or exclusions to any given evidence" (5.2)
- "Data that inform an artifact can be found and accessed" (4.4)
- "Metadata captures the dates an artifact was first and last published..." (6.3)

It is expected that the metadata fields, as well as their descriptions, will continue to be refined as a greater variety of content is added to the Repository.

6.2 Repository Contributions

The CDS Connect Repository currently hosts 56 evidence-based CDS artifacts contributed by a variety of Federal agencies, Federal contractors, academic and research institutions, and healthcare organizations. Contributors had two methods for contributing CDS to the Repository: (1) use the API described in Section 6.1.1 to upload their artifact(s) to the Repository or (2) enter the metadata describing their CDS contribution manually, attaching relevant supporting documents and coded logic via a webform. The CDS Connect team assisted all contributors with the upload of their artifacts and performed a review of each contribution prior to publishing it on the Repository. The review included an evaluation of each coded expression to ensure that it was described appropriately in the metadata and included all relevant technical files. The team also performed a clinical review of each entry to evaluate whether the proposed metadata responses remained consistent across each metadata field and aligned with the clinical evidence-based source. Many contributions went through multiple iterations before the CDS Connect team and contributor agreed that it was ready to publish.

The list of published entries on the CDS Connect Repository as of September 2019 is available in <u>Appendix B</u> of this report.

Task 7: Prototype Authoring Tool

In year 1 of the CDS Connect project, the project team built the initial prototype of the CDS Authoring Tool. The primary goal of the AT is to allow people unfamiliar with CQL to develop structured, well-formatted CQL artifacts with a friendly user interface (UI). At the end of the first year, the AT was proof-of-concept software. It supported the necessary features for the first year, but it was completely open access (i.e., it had no user accounts), had inconsistent style with the CDS Connect Repository, and was not yet released to the public. In addition, it only supported a limited set of data elements, focusing mainly on the domain of cholesterol management. The year 1 tool proved the concept of user-friendly CDS authoring, but it was not yet useful to the general CDS community.

In year 2, the AT team worked to resolve many of the limitations in the initial version of the software. The AT was publicly released in November 2017, with support for individual user

accounts and an updated UI. After the public release, the CDS Connect team updated the AT to support a more general approach for building data elements. To build a data element, users could choose a broad data element type (e.g., condition, procedure, observation, etc.) and then set its topic by searching and selecting a value set or clinical code from the NLM's VSAC. This approach allowed for authors to create new CDS artifacts across a wide variety of clinical domains. In addition, the project team introduced a new testing capability to allow users to execute their CDS logic against synthetic patients. By the end of year 2, the AT was production-level software with 89 registered users and was available under an Apache 2.0 open-source license on the AHRQ-CDS-Connect-Authoring-Tool GitHub project.

7.1 Authoring Tool Enhancements

In the third year of the project, the AT team focused on improving the authoring experience by enhancing the UI, facilitating reusability, supporting an additional version of FHIR (STU3), importing and referencing external CQL libraries, allowing users to annotate data elements, and expanding the testing capabilities. These features were developed in the context of 2-week development cycles with input from AHRQ and the CDS Connect WG.

7.1.1 Updated Landing Page

The AT's UI was updated throughout the year based on user feedback and recommendations from design reviews. As part of this effort, the CDS Connect team revamped the landing page to provide a cleaner and more engaging introduction to the AT. The new landing page also features a "What's New" section that highlights major updates and events related to the AT, as displayed in **Figure 14**.

U.S. Department of Health & Human Services AHRQ Home About AHRQ Contact AHRQ FAQ

■Email Updates Agency for Healthcare Research and Quality % CDS Home PATIENT-CENTERED OUTCOMES RESEARCH Login **Clinical Decision Support Authoring** Sign Up Feedback Documentation Create shareable standards-based CDS artifacts The Clinical Decision Support (CDS) Authoring Tool is a component of the CDS Connect project SIGN UP Statin Use for the Prevention of CVD in Adults External CQL CDS Authors can now import externally authored CQL libraries and use their defined expressions in Inclusions, Exclusions, Subpopulations, and Base Elements. This allows authors to fill gaps in logic that cannot be produced by the CDS Authoring Tool and to leverage pre-existing CQL expressions. 1.0.2 (DSTU2) 1.0.2 1.0.2 (DSTU2)

Figure 14. CDS AT: Updated Landing Page

7.1.2 Workspace Descriptions and Expression Phrases

To assist new users of the tool, the CDS Connect team updated each tabbed workspace to display a brief description of its purpose and use. For example, the "Inclusions" tab contains the following description: "Specify criteria to identify a target population that should receive a recommendation from this artifact. Examples might include an age range, gender, presence of a certain condition, or lab results within a specific range." Within the workspaces, each element displays an "expression phrase" that describes the constructed logic in user-friendly terms (**Figure 15**).

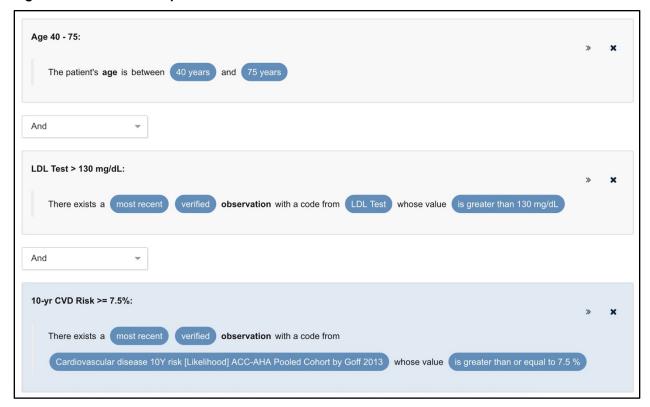
 Download CQL ▼ Save **Pain Management Summary** Inclusions Base Elements Recommendations Handle Errors External CQL Exclusions Subpopulations Parameters Specify individual elements that can be re-used in the Inclusions, Exclusions, and Subpopulations, or should standalone as independent expressions in the resulting artifact. An example might be a lab result value that is referenced multiple times throughout the artifact workspace description Observation: **FACES Assessments** observations with a code from Pain severity Wong-Baker FACES pain rating scale which occurred within the last 2 years expression phrase Comment: Code: LOINC (38221-8) - Pain severity Wong-Baker FACES pain rating scale Verified Expressions: 2 Year(s) × ✓ List Of Observations Return Type: Add Expression ■ Add Value Set (Add Code

Figure 15. CDS AT: Workspace Descriptions and Expression Phrases

7.1.3 Collapsible Elements and Groups

To allow users to more easily see the full context and relationship of data elements within a workspace tab, the AT team added support for collapsing elements and groups. When an element or group is collapsed, only the element name and expression phrase is displayed, allowing the user to see a brief summary of the collapsed content (**Figure 16**).

Figure 16. CDS AT: Collapsed Elements



7.1.4 Parameter Enhancements

In the CDS Authoring Tool, authors are able to specify "parameters" that integrators may want to adjust based on individual site preferences. For example, an artifact that is capable of providing Grade B and Grade C recommendations may contain a parameter to control whether or not Grade C recommendations are returned. In year 3, the team also enhanced the usability of parameters in the AT. In addition to improving parameter expression phrases, the AT now prevents authors from deleting or modifying parameters in any way that might break existing parameter uses. A number of new expression modifiers have also been added to allow parameters to be used in more meaningful ways. For example, integer, decimal, and quantity parameters can be compared against known values; datetime parameters can be compared against other dates at user-specified precisions; and interval parameters can be tested for containment of a point within the interval.

7.1.5 Base Elements

The new "Base Elements" feature allows authors to create data elements beyond the context of inclusion, exclusion, or subpopulation criteria. These base elements can be reused throughout the CDS logic or serve as standalone elements to be used for other purposes (e.g., data to display in a dashboard). Base elements can be simple elements (e.g., a most recent lab test), or complex elements using nested <u>Boolean logic</u> (i.e., and/or), unions, or intersections of lists. Base elements enhance the AT's reusability, allowing authors to define an element once and reference it

wherever it is needed throughout the artifact. When a base element is referenced (**Figure 17**), it can be used as is, or it can be further refined using expression modifiers. For example, an author can reference a base element that represents the "10-yr CVD Risk" as an Observation value. If the author wishes to use it within inclusion criteria, the author can then add an expression modifier to indicate that the "10-yr CVD Risk" should be greater than or equal to 7.5 percent (**Figure 18**). Authors can also navigate to all uses of the base element from the base element definition and navigate to the base element definition from any element that uses it. In addition to supporting reusability, base elements also allow the AT to more easily support other types of CDS, such as the Pain Management Summary SMART on FHIR dashboard.

Figure 17. CDS AT: Selecting a Base Element



Figure 18. CDS AT: Adding an Expression Modifier to a Base Element Reference



7.1.6 HL7 FHIR STU3

While the CQL specification allows CQL logic to be authored using any data model, most CDS artifacts authored in CQL use HL7 FHIR as the data model. HL7 FHIR currently has three major versions, referred to as DSTU2, STU3, and Release 4 (R4). The initial versions of the CDS Authoring Tool supported HL7 FHIR DSTU2 since it has the best adoption and support in the marketplace. Near the end of year 2, the AT was capable of exporting and executing CQL that

used the FHIR DSTU2 data model. In year 3, the team evaluated approaches to supporting both FHIR DSTU2 and STU3 concurrently. One approach required authors to lock artifacts to a specific version of FHIR when they are created, while the other approach allowed authors to choose the FHIR version when artifacts are downloaded. While the former approach would allow for more version-specific features in the AT, the CDS Connect team chose the latter approach due to its flexibility. CDS authors can now download any artifact using a FHIR DSTU2 or STU3 model (**Figure 19**) and can test artifacts against FHIR DSTU2 and/or STU3 synthetic patients. This approach can also be applied in a future version of the CDS Authoring Tool to support FHIR R4.

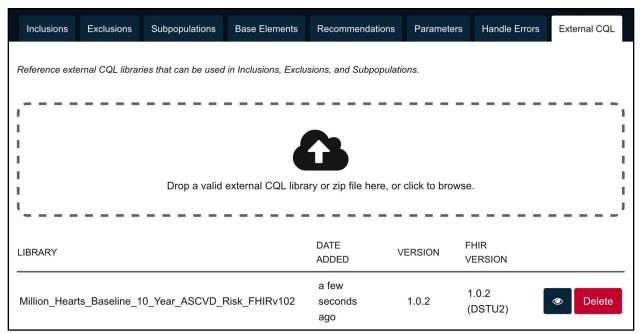
Figure 19. CDS AT: Downloading Using HL7 FHIR STU3



7.1.7 Importing External CQL Libraries

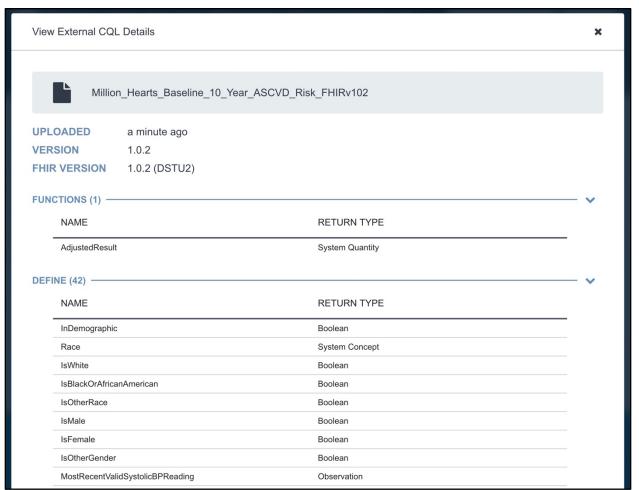
Near the end of year 3, the AT team added support for importing and referencing external CQL files. Because the AT is designed for ease of use, and because the CQL specification is quite robust, it is unlikely that the tool will ever support every capability of the CQL language. For this reason, authors may need to create portions of CQL outside of the tool to handle capabilities not yet authorable in the tool. Authors may also want to leverage existing CQL libraries developed by other authors or organizations. To support this capability, the AT now allows external CQL libraries to be imported into the tool and then referenced from elements in the workspace (**Figure 20**). If an external CQL library has no dependencies on other libraries, authors can import it as a single file; otherwise they must import it as a zip file containing the library and all of its dependencies.

Figure 20. CDS AT: External CQL Workspace



After uploading an external CQL library, authors are able to view its details, including a listing of all available definitions and their return types (**Figure 21**). While the details page lists functions and define statements, the CDS AT currently only supports referencing define statements in the CDS logic. Future versions of the CDS AT may support referencing external functions as well.

Figure 21. CDS AT: View External CQL Details



7.1.8 Referencing External CQL Libraries

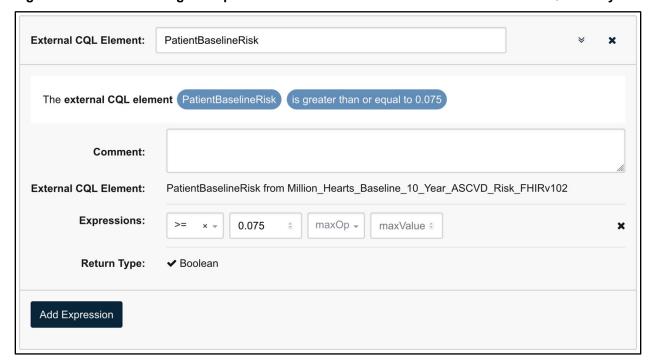
Once an external CQL library has been imported into the CDS AT, authors may reference its elements from the CDS AT workspaces. To do this, the authors first choose the library by its name and then choose an element within the library (**Figure 22**).

Figure 22. CDS AT: Selecting an Element from an External CQL Library



As is the case with Base Elements, authors can further manipulate the referenced element by adding expression modifiers to it. For example, if the external CQL element represents "PatientBaselineRisk" as a decimal, the author can add an expression modifier to determine if its value is greater than or equal to 0.075 (**Figure 23**). This allows for greater flexibility in the use of data elements from external CQL libraries.

Figure 23. CDS AT: Adding an Expression Modifier to an Element from an External CQL Library



7.1.9 Annotating Elements with Author Comments

In the process of authoring CDS logic, authors often annotate their logic with human-readable comments. These comments allow others to understand the logic better by documenting decisions that were made during authoring, providing a summary of complex logic, noting a source, providing reference URLs, or even calling attention to logic that should be localized for specific sites. In year 3, the CDS Connect team added a capability to allow authors to easily add

comments to data elements within the CDS AT (**Figure 24**). These comments are retained in the downloadable CQL representations so that implementers can benefit from the author's comments as they review the formal CQL logic (**Figure 25**).

Figure 24. CDS AT: Annotating and Element with Author Comments

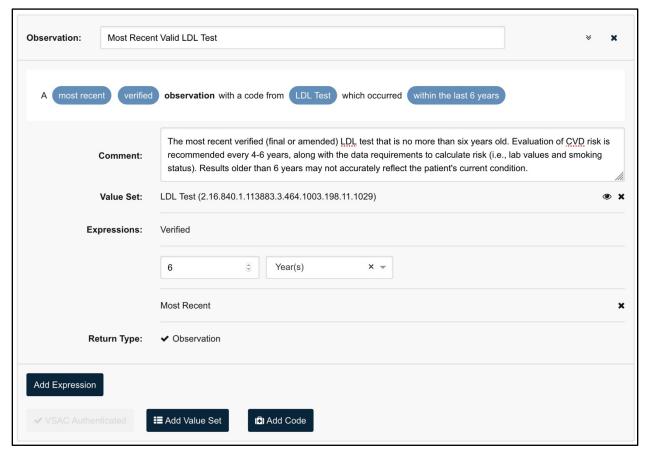


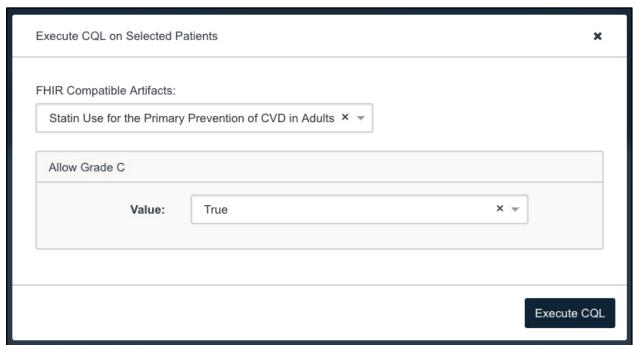
Figure 25. CDS AT: Representation of Author Comments in Downloaded CQL

```
// The most recent verified (final or amended) LDL test that is no more than six years old. Evaluation of
// CVD risk is recommended every 4-6 years, along with the data requirements to calculate risk (i.e., lab
// values and smoking status). Results older than 6 years may not accurately reflect the patient's current
// condition.
define "Most Recent Valid LDL Test":
    C3F.MostRecent(C3F.ObservationLookBack(C3F.Verified([Observation: "LDL Test VS"]), 6 years))
```

7.1.10 Testing Enhancements

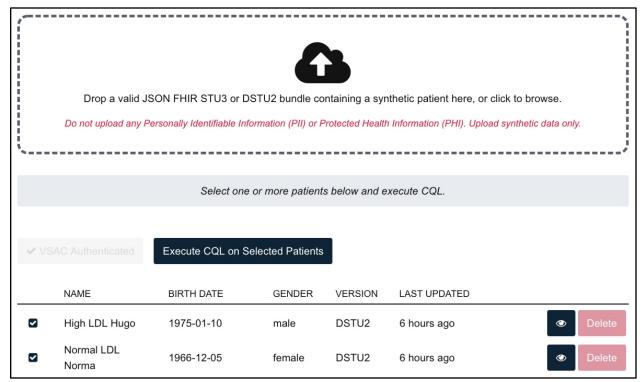
The CDS Connect team also enhanced the AT's testing capability in year 3 of the project. Now authors are able to specify parameter values when testing CQL artifacts against synthetic patients (**Figure 26**). Prior to this change, the testing component of the tool always used the default value for parameters, but authors can now test logic using non-default values as well. This allows authors to verify logic that should behave differently based on parameter values.

Figure 26. CDS AT: Testing a CDS Artifact with a Specific Parameter Value



In addition, the team updated the testing capability at the end of year 3 to allow CQL authors to test an artifact against multiple synthetic patients at the same time (**Figure 27**). This updated capability is much more efficient than testing synthetic patients one at a time, and it also allows for easier comparison of results between different synthetic patients.

Figure 27. CDS AT: Testing a CDS Artifact Against Multiple Patients



7.1.11 Community Engagement

Feedback regarding the AT has been positive, and demonstrations have attracted attention at conferences such as the AMIA Annual Symposium, HIMSS conferences, and the MCBK Annual Meeting. In addition, the CDS Authoring Tool was featured in a national webinar that was attended by approximately 300 people and garnered significant interest. Over the course of the third year, 99 new users signed up for the CDS Authoring Tool, bringing the overall total to 188 registered users (as of August 7, 2019).

Lessons Learned

Through the third year of the CDS Connect project, the CDS Connect project team recorded several valuable lessons. Each lesson impacted year 3 work and provided valuable insight for future CDS efforts.

- 1. Lessons Learned affecting the development of and enhancements to CDS Connect prototype tools:
 - The availability of public terminology servers: The CDS Connect team initially planned to add support for additional terminology servers in the AT during year 3. After investigation and discussion with the CDS Connect WG, however, the team was unable to identify any publicly available terminology servers that would add significant value. One server only supported value sets that were part of the FHIR

core specification, another contained out-of-date value sets and a difficult-to-use API, and a third was intended for a different jurisdiction and required licensing fees to use within the United States. Organizations using the AT to author CDS logic may need to choose between using VSAC or standing up their own terminology server and modifying the CDS Authoring Tool source code appropriately.

- Support for intensional value sets in VSAC: The human-facing VSAC web interface gained support for intensional value sets during the 2018-2019 period of performance. Intensional value sets allow authors to define value sets using rules instead of enumerating each code in the value set. However, the VSAC FHIR API provided by the NLM has not yet been updated to support intensional value sets. This affects the AT's ability to display and execute intensional value sets. VSAC FHIR API consumers need to be aware that the VSAC FHIR API may trail behind the web interface and Sharing Value Sets 2 API when new features are introduced.
- **CQL dependencies and common libraries:** If a primary CQL library and its dependencies both require a common library, they must agree on the version of that library. For example, if LibraryA depends on LibraryB and LibraryC, and LibraryB also depends on LibraryC, then LibraryA and LibraryB must use the same version of LibraryC. While the CQL 1.3 specification was not clear about this situation, the CQL 1.4 specification explicitly states that all references to the same library must use the same version.⁴ As such, authors need to be careful about matching versions in dependency libraries.
- The benefits of automated tests for CDS logic: The CDS Connect team built and leveraged the CQL Testing Framework prototype tool to support the development of automated tests for the CDS artifacts piloted in year 3. Utilizing this approach improved the efficiency of CQL development, allowing the authors to catch bugs early, to validate edge-case scenarios, and to have confidence in the final CQL logic. The automated tests also benefitted the pilot with b.well in several ways. First, because the CDS Connect team thoroughly tested the CDS logic before delivering it to b.well, b.well did not discover any bugs in the CDS logic during pilot preparation or execution. Second, b.well was able to reference hundreds of test cases as example data inputs and expected results during their integration. Third, b.well was able to leverage the generated client tests (using the popular Postman API testing tool) to validate that their CQL Services instance was correctly installed and configured.
- 2. Lessons learned throughout the CDS pilot process:
 - The volume of "real-world" data: During the pilot, the CQL Services software failed to return results for several patients due to the volume of data for each patient. While issues with data volume did not come up in testing, it did prove to be an issue for a handful of patients in production. The CDS Connect team addressed the issue by

increasing the default size limit of incoming messages in CQL Services and providing a way for the size limit to be configured on site. Implementers should assess the volume of data that might be used in their implementation and ensure they have tests to validate that their integration works when approaching those upper limits.

- Aggregating data from multiple sources: b.well received end-user data from multiple sources, including claims, EHRs, PBM systems, reference laboratories, and PGHD (e.g., data from wearable devices, surveys and questionnaires, and mobile applications). While this rich source of data provided additional opportunities for ensuring greater coverage of required data elements, multiple gaps were identified in the completeness and specificity of the required data available on the b.well platform. For example, more than 85 percent of lab results did not contain Logical Observation Identifiers Names and Codes (LOINC) codes, the standard terminology for lab results; and more than 95 percent of medications were represented by a National Drug Code (NDC) instead of RxNorm, the standard terminology used for clinical drugs. To address this, b.well had to perform extensive data mapping of local, non-standard data to standard codes for the CDS logic to appropriately evaluate patient data in the pilot site's system. Implementers should recognize that multiple sources of data may compound the mapping effort and need to assess the data available for potential gaps in definition and specificity.
- The impact of extensive data mapping: Related to data aggregation and the potential need for extensive mapping, b.well estimated that data mapping consumed nearly 25 percent of their engineering resource hours, equaling about 80 hours, with another 20 hours required for clinical and data analytics expertise. Future pilot efforts should consider this mapping effort when developing an integration and implementation timeline and ensure access to clinical informaticists familiar with standard terminologies and the FHIR data model to assist in these efforts. In addition, the health IT industry would benefit greatly from broader adoption of standardized terminologies and the FHIR data model, supporting increased interoperability and aggregation of data.
- Integration and pilot FHIR support: The b.well technical team had no experience with CQL or CDS Hooks, and limited experience with FHIR. This was not surprising given the relative newness of these standards. This made the aggressive integration timeframe even more challenging. Although the CDS Connect team provided documentation, tools, and technical support to assist b.well in these efforts, the pilot timeline proved challenging for the b.well technical resources. In future pilot efforts, the experience of the pilot technical team with FHIR and other standards should be considered during the technical evaluation and planning stages and accounted for in the final workplan.

- Engaging patients as CDS end users: Patient-facing, evidence-based CDS may ultimately be one of the most effective methods of improving health outcomes by providing evidence-based information directly to patients and connecting them to resources and tools. The CDS pilot benefitted from the experience and expertise of b.well in providing patient-facing health management resources and tools. However, due to the tight implementation timeline, there were limited opportunities to engage the b.well end users to provide feedback on educational materials and other pilot aspects. b.well also desired to personalize the recommendations provided to each end user to include individual risk factors identified by the CDS but were unable to accomplish this within the integration timeframe. Future patient-facing CDS pilots should consider the importance of selecting a pilot partner with consumer/patient-facing experience and expertise, as well as ensuring that the pilot timeframe allows personalization and engagement opportunities to be realized.
- 3. Lessons learned affecting CDS artifact development:
 - Ongoing maintenance of VSAC value sets: The CDS Connect team desired to reuse value sets already available on VSAC and not create new, similar value sets, if possible. Although the team identified many value sets that met the high-level definition of required clinical concepts, further analysis revealed that some had not been updated to account for new terminology code set releases, or terminology codes were missing, even if updates had been applied. Currently the VSAC lacks any defined oversight process for value set creation and maintenance, leading to imprecisely defined, missing, or invalid codes within some value sets. Because implementers cannot trust that existing value sets from other stewards are maintained, they often create new value sets representing the same or similar concepts. A governance process to help ensure the validity and maintenance of available value sets found on VSAC would increase trust and improve value set reuse while decreasing the number of "similar" value sets created.
 - Informing CDS development through an environmental scan: An environmental scan at the outset of project activities provided key information to help shape project strategy and decision making. The findings informed many aspects of the project, including the selection of the pilot partner and the focus of the preventive care CDS recommendations. An effective environmental scan should research the identified clinical domain, relevant evidence-based sources, existing CDS interventions, past lessons learned, previously identified challenges, and potential constraints. The year 3 environmental scan was especially beneficial as the CDS Connect team explored the use of health IT by consumers/patients and relevant information on patient-facing CDS.

- Collaboration with knowledge authors: Having knowledge authors participate in the translation of the evidence to CDS expression enables clinicians and members of a multi-disciplinary CDS development team to accurately translate and represent the evidence-based knowledge, driving delivery of evidence-based CDS interventions.
- befining clinical "conditions" when historical data is required: Although many health systems are currently using either International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) or Systematized Nomenclature of Medicine-Clinical Terms (SNOMED-CT) codes to store and represent a diagnosis (i.e., "condition"), some legacy ICD-9-CM codes remain in health IT systems and patient records. When defining clinical concepts in CDS logic, if the lookback period specified in CDS logic requires patient data recorded prior to the implementation of ICD-10-CM (i.e., looks for patient data recorded prior to 10/1/2015 when the use of ICD-10-CM was mandated), it is prudent to include ICD-9-CM codes in the concept definitions to ensure that all relevant patient data is evaluated by the CDS logic.
- 4. Increasing feedback and awareness through stakeholder engagement:
 - The value of WG feedback: The varied, real-world experience and insight of WG members provided major value to the CDS Connect project efforts. Ensuring that systems and resources produced by CDS Connect are informed by stakeholder feedback amplifies the usefulness, usability, and longevity of the systems.
 - Engaging the stakeholder community: Engagement via outreach, collaboration, partnerships, discussions, and conference presentations provides AHRQ and the project team with opportunities to introduce the CDS Connect project, systems, and tools to the healthcare community. It also aids in spurring contributions to the Repository and use of the AT, increasing the likelihood of sustained use of the systems.

Recommendations

The CDS Connect team recommends the following activities be considered when planning future CDS Connect activities:

- 1. **Continue stakeholder outreach:** Presentations at conferences, webinars, and meetings enable the project team to introduce the CDS Connect mission and systems to new stakeholders, identify new CDS contributors and end users of shared CDS, and explore sustainability approaches for CDS Connect software and resources.
- 2. **Support FHIR R4 in the CDS Authoring Tool and prototype tools:** While FHIR DSTU2 currently enjoys the most industry adoption, FHIR Release 4 (R4) is gaining support, particularly because some resources within it now have "normative" status. Resources with "normative" status are guaranteed to remain stable, thereby lowering the

- risk that implementations of them will become obsolete as the FHIR specification evolves. The AT should support exporting artifacts as FHIR R4 and should consider aligning data element names with FHIR R4 resource names where appropriate. CQL Services and the CQL Testing Framework should also be updated to support testing and executing CQL that uses the FHIR R4 data model.
- 3. **Update CQL Services to conform to CDS Hooks 1.0 final release:** CQL Services is currently based on a pre-1.0 version of CDS Hooks that was used to gather feedback from the standards community. Now that CDS Hooks 1.0 has been released, CQL Services should be updated to reflect it. In addition, the development team should consider implementing dynamic querying for FHIR resources to avoid the requirement that all data be sent as part of the initial service request (i.e., as "prefetch" data).
- 4. **Update the CQL Testing Framework to support all FHIR resource types:** Currently, the CQL Testing Framework supports a subset of FHIR resource types and properties. Ideally, the CQL Testing Framework would allow test data to be defined using all available FHIR resources and properties. If this capability is not feasible, the current set of resources and properties should at least be expanded.
- 5. Continue to track industry movement and adoption of FHIR STU3 and R4 data models. Consider updates to artifacts developed by CDS Connect over the past 3 years based upon vendor system adoption of these data models.

Appendix A. Key Activities and Work Products for Each Project Task

The CDS Connect project had seven interrelated tasks within which all work was performed. The following list enumerates those tasks, along with their key activities and work products.

1. Task Management

- a. Key activities: Led leadership meetings; led sprint planning and burndown meetings; led sponsor engagement; managed staff, project finances, and deliverables; led stakeholder outreach and engagement; collaborated with the CDS community.
- b. Key work products: Leadership meeting agendas and briefings; sprint meeting notes; CDS Connect briefings, conference, and outreach presentations; project work plan; final variance report; final project report.

2. Develop PCOR CDS Artifacts

- a. Key activities: Researched the preventive health domain; developed relevant CDS approaches to support preventive health; translated recommendation statements from the U.S. Preventive Services Task Force (USPSTF) into CDS; collaborated with USPSTF subject matter experts (SMEs) to validate CDS approaches and logic; analyzed existing value sets to define clinical concepts in the logic, and developed new value sets where needed; documented decisions in a decision log; developed and tested interoperable CDS logic for four CDS artifacts; performed multidisciplinary quality reviews on each artifact; created detailed implementation guides to accompany each artifact on the Repository; enhanced the CQL expression based upon pilot findings.
- b. Key work products: Environmental scan; intellectual property report; four new structured artifacts for publication on the Repository; textual reports for new and updated artifacts; implementation guides for each new artifact; an "enhanced artifact" report.

3. Pilot PCOR CDS Artifacts

a. Key activities: Developed a pilot plan; defined ideal pilot site characteristics and identified ideal pilot organizations; performed outreach to potential pilot organizations; conducted an analysis of interested organizations; discussed the potential pilot organizations with AHRQ and assisted with pilot site selection; secured Institutional Board Review (IRB) approval; developed a pilot work plan and led the pilot kickoff meeting; developed a detailed data requirements spreadsheet and mapping guide; led weekly operational and technical calls; assisted b.well with content development for CDS intervention notifications and educational materials; developed an analytic plan and end-user survey questions; assisted b.well with integration, testing, and implementation tasks; participated in

- troubleshooting and resolution of issues as they arose; developed a pilot final report.
- b. Key work products: Pilot plan; executed contract with b.well; IRB approval; pilot work plan; pilot analytic plan; data requirement spreadsheet; pilot final report.

4. Develop Prototype Tools for Sharing PCOR CDS Artifacts

- a. Key activities: Identified a list of potential prototype tools for development; collaborated with the CDS Connect WG to select a prototype tool and determine requirements; developed a prototype tool (CQL Testing Framework) that enables CQL authors to develop and execute test cases for validating CQL-based CDS logic; prepared for and released the prototype tool (CQL Testing Framework) as open-source software on GitHub; enhanced the year 2 prototype tool (CQL Services) to better support year 3 pilot implementation.
- b. Key work products: Alpha, beta, and production-level prototype tool (CQL Testing Framework); CQL Testing Framework source code on GitHub; associated documentation and WG briefings; multiple updated releases of the year 2 prototype tool (CQL Services).

5. Maintain Stakeholder Work Group

- a. Key activities: Recruited WG members; developed and shared an updated WG charter; identified a WG chairperson; developed and disseminated monthly agendas, presentations, and meeting summaries; obtained continuous, open-source collaboration approval for public release of all WG documents; collaborated with WG members via email to further project objectives; maintained a list of all WG members.
- b. Key work products: WG charter; meeting agendas; presentations; meeting notes; final list of WG members and their organizations.

6. Host and Maintain Prototype Tools

a. Key activities: Applied several software updates to the CDS Connect Repository, including a major upgrade to the underlying Drupal web application and several critical security patches; facilitated user account setup and maintenance; collaborated with the Veteran's Health Administration (VHA) to have their large collection of CDS artifacts published on the Repository; collaborated with the CMS Center for Program Integrity (CPI) to enable the Durable Medical Equipment (DME) Electronic Prescribing (eRx) project to use the CDS Connect Repository as the backend for the Documentation Requirement Lookup Service (DRLS) pilot; achieved open-source status of the Repository API (enabling stakeholders to study, use, and improve upon the code); facilitated the DRLS pilot and other third-party contributions; designed, tested, and deployed "Artifact Discovery;" incorporated the Medical Subject Headings (MeSH) taxonomy as a

- mechanism for tagging CDS artifacts with pertinent topics; revamped menus to expose several new pages, including: Patient's Perspective blog, Technical Resources page, and Collaborations page; expanded user accounts to address Trust Framework Work Group (TFWG) recommendations.
- b. Key work products: Publicly accessible instance of the Repository and CDS Authoring Tool at https://cds.ahrq.gov; updated source code for the production version of the Repository; bimonthly updates to CDS Connect Systems Document; biannual updates to the Service Level Agreement document; CDS Connect API; released as an open source Drupal module on GitHub; Repository Enhancement Discussion (Technical Briefing); CDS Connect and the Health Level 7 (HL7) Da Vinci Project (Technical Briefing).

7. Prototype Authoring Tool and Related APIs

- a. Key activities: Planned, developed, and released three rounds of enhancements to the AT; revamped the AT landing page; improved usability via collapsible elements and enhanced expression phrases; allowed authors to annotate elements with custom comments; added support for reusable "base elements;" expanded the testing capability to support specifying parameter values and multi-patient testing; enabled authors to import and reference externally authored CQL; added support for Fast Healthcare Interoperability Resources (FHIR) Standards for Trial Use 3 (STU3); implemented various bug fixes and security patches; demonstrated the AT in a national webinar and multiple conferences; facilitated user account setup and maintenance.
- b. Key work products: Multiple new releases of the CDS AT; source code updates on GitHub; automated unit tests; associated documentation updates and briefings; bimonthly updates to the CDS Connect Systems Document; biannual updates to the Service Level Agreement document.

Appendix B. CDS Connect Repository Artifact Manifest

The following table lists every artifact published on the CDS Connect Repository as of September 2019, along with the artifact's Steward (i.e., the organization that sponsored the artifact's creation), the knowledge level, and the original date that the artifact was published on the CDS Connect Repository.

Table 2. List of Repository Artifacts

Artifact Name	Steward	Knowledge Level	Date Published
Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Part Two, Counseling	AHRQ	Structured	9/11/2019
Abnormal Blood Glucose and Type 2 Diabetes Mellitus: Part One, Screening	AHRQ	Structured	9/11/2019
Anthrax Post-Exposure Prophylaxis	CDC	Structured	10/25/2018
Aspirin Therapy for Primary Prevention of CVD and Colorectal Cancer	AHRQ	Semistructured	07/10/2017
Clostridoides Difficile (C. diff) Infection (CDI) Treatment Pathway	University of Pennsylvania Health System	Semistructured	04/16/2018
CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Baseline 10-Year ASCVD Risk	AHRQ	Structured	02/1/2018
CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Shared Decision Making	AHRQ	Semistructured	08/22/2017
CMS's Million Hearts® Model Longitudinal ASCVD Risk Assessment Tool for Updated 10-Year ASCVD Risk	AHRQ	Semistructured	08/22/2017
Endocrinology: Hypoglycemia	VHA	Structured	02/26/2019
Endocrinology: Hypoglycemia Documentation Template	VHA	Structured	04/20/2018
Endocrinology: Hypoglycemia Order Set	VHA	Structured	04/20/2018
Endocrinology: Hypoglycemia Rule	VHA	Structured	04/20/2018
Eye Care Documentation Template	VHA	Structured	04/26/2018
Factors to Consider in Managing Chronic Pain: A Pain Management Summary	AHRQ	Structured	06/1/2018

Artifact Name	Steward	Knowledge Level	Date Published
Healthful Diet and Physical Activity for Cardiovascular Disease Prevention in Adults With Cardiovascular Risk	AHRQ	Structured	09/11/2019
Healthy Weight Care Assistant	СНОР	Structured	10/22/2014
Immunication Calculation Engine (ICE)	HLN Consulting, LLC	Executable	6/10/2018
Interventions for Unhealthy Alcohol Use: SmartSet for Note Documentation, Referrals, and Medications	AHRQ	Semistructured	10/31/2018
Management of Community-Acquired Pneumonia in Adults	NORC at the University of Chicago, Yale University	Semistructured	07/31/2017
Mental Health: Consult for Depression	VHA	Structured	06/11/2018
Mental Health: Consult for Depression Documentation Template	VHA	Structured	04/11/2018
Mental Health: Consult for Depression Order Set	VHA	Structured	04/9/2018
Mental Health: Homelessness Documentation Template	VHA	Structured	03/27/2018
Mental Health: Iraq & Afghan Post-Deployment Screen Order Set	VHA	Structured	04/9/2018
Mental Health: Iraq & Afghanistan Post-Deployment Screen - Reminder to Perform Screening Rule	VHA	Structured	04/27/2018
Mental Health: Iraq & Afghanistan Post-Deployment Screen - Rule to Create Appropriate Order Set Rule	VHA	Structured	04/9/2018
Mental Health: Iraq & Afghanistan Post-Deployment Screen Documentation Template	VHA	Structured	04/9/2018
Mental Health: Positive Suicide Risk Screening Order Set	VHA	Structured	04/27/2018
Mental Health: Suicide Risk Assessment Documentation Template	VHA	Structured	04/6/2018
Neurology: Traumatic Brain Injury (TBI)	VHA	Structured	05/8/2018
Neurology: Traumatic Brain Injury (TBI) - Polytrauma Interdisciplinary Rehab Clinic Order Set	VHA	Structured	04/3/2018
Neurology: Traumatic Brain Injury (TBI) Documentation Template	VHA	Structured	05/25/2018

Artifact Name	Steward	Knowledge Level	Date Published
Neurology: Traumatic Brain Injury (TBI) Screening Documentation Template	VHA	Structured	04/3/2018
Neurology: Traumatic Brain Injury (TBI) Screening Rule	VHA	Structured	04/3/2018
Neurosurgery Radiculopathy (Cervical)	VHA	Structured	06/22/2018
Neurosurgery Radiculopathy (Lumbar Thoracic)	VHA	Structured	06/22/2019
Neurosurgery: Radiculopathy (Cervical) Documentation Template	VHA	Structured	07/17/2017
Neurosurgery: Radiculopathy (Cervical) Order Set	VHA	Structured	07/17/2017
Neurosurgery: Radiculopathy (Lumbar Thoracic) Documentation Template	VHA	Structured	06/20/2018
Neurosurgery: Radiculopathy (Lumbar Thoracic) Order Set	VHA	Structured	06/20/2018
Occupational Factors Impacting Diabetes	National Institute of Occupational Safety and Health	Structured	02/28/2018
Primary Care: Anaphylaxis Treatment Protocol Order Set	VHA	Structured	04/4/2018
Primary Care: Family Health History Documentation Template	VHA	Structured	03/7/2018
Primary Care: General Clinical Note - History and Physical Exam Documentation Template	VHA	Structured	03/26/2018
Primary Care: Tobacco Assessment and Cessation Counseling Documentation Template	VHA	Structured	03/21/2018
Recommendation #4 - Opioid Release Rate When Starting Opioid Therapy	CDC	Structured	09/27/2018
Recommendation #5 - Lowest Effective Dose	CDC	Structured	04/23/2017
Recommendation #7 - Opioid Therapy Risk Assessment	CDC	Structured	09/27/2018
Recommendation #8: Naloxone Consideration	CDC	Structured	09/27/2018
Recommendation #10 - Urine Drug Testing	CDC	Structured	04/23/2017
Recommendation #11: Concurrent Use of Opioids and Benzodiazepines	CDC	Structured	09/27/2018

Artifact Name	Steward	Knowledge Level	Date Published
Refugee Health Decision Support	СНОР	Structured	11/1/2017
Rheumatology: Psoriatic Arthritis Order Set	VHA	Structured	01/5/2018
Screening and Interventions for Unhealthy Alcohol Use: Logic for Best Practice Alerts	AHRQ	Semistructured	10/31/2018
Statin Therapy for the Prevention and Treatment of Cardiovascular Disease (CVD) eCQM	AHRQ	Structured	07/10/2017
Statin Use for the Primary Prevention of CVD in Adults: Clinician-Facing CDS Intervention	AHRQ	Structured	07/10/2017
Statin Use for the Primary Prevention of CVD in Adults: Patient-Facing CDS Intervention	AHRQ	Structured	09/11/2019

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